

Second Edition

Introduction to

Acute & Ambulatory Care

PHARMACY PRACTICE

David A. Holdford

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Acute & Ambulatory Care

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Previously published as *Introduction to Hospital
and Health-System Pharmacy Practice*

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When I was a child living in Mount Vernon, Ohio, I visited my father at his workplace in the pharmacy of Mercy Hospital, a small Catholic hospital serving the rural community. My dad, Arthur A. Holdford, RPh, was the director of pharmacy services. In fact, he was the only pharmacist employed by Mercy Hospital at the time. Large pharmacy staffs were not common when he first took the job at the hospital. Over time, he was able to hire employees to support the expansion of pharmacy services.

The hospital where my father worked was very different from today's hospitals. Back then, there were no computers, no Internet, and no automated dispensing cabinets. Handling, storage, and administration of sterile products and other medicines were primitive compared to today. Nurses prepared intravenous drugs on the floors using subpar aseptic technique. Oral medications were typically sent in bulk bottles to nursing units to be administered, with little pharmacy oversight or input. Medication-use systems were neither very safe, nor were they really systems.

Clinical pharmacy, as we now know it, was in its infancy back then. Clinical pharmacists were rarely seen in hospitals. Today's most commonly used drugs had not yet been invented. Major diseases, including AIDS, were not known either.

The hospital where my father worked was not part of an integrated health system, so it did not coordinate its care with a network of outpatient clinics, physicians' offices, pharmacy benefits management, long-term care facilities, home health agencies, and the like. My father worked in a hospital, not a health system.

Medicare and Medicaid were just in their infancy at that time. Pharmacy benefits managers and many other forms of managed care were virtually nonexistent. Pharmacists were not as well paid as today's pharmacists. Pharmacist training was also different. Pharmacists needed fewer years of schooling, and their education revolved around the product versus the patient. In short, a lot has changed since my father's days.

Individuals entering the pharmacy profession today will see some truly amazing changes in healthcare and pharmacy practice during their career. It is impossible to accurately predict the exact nature of those changes, just as it would have been impossible for my father to imagine the changes that would occur over his lifetime. The only certainty is that change will continue, and pharmacists will be a part of it.

Origin of this Text

The first edition of this text, *Introduction to Hospital and Health-System Pharmacy Practice*, originated from another, *Handbook of Institutional Pharmacy Practice*. The *Handbook*, first published in 1979 by Drs. Thomas Brown and Mickey Smith, went through four editions before sparking the origin of this book.

Introduction to Hospital and Health-System Pharmacy Practice covered many of the same topics and concepts as the original *Handbook*, but it was written for a new audience—pharmacy students, educators, technicians, and new pharmacy graduates. Content and pedagogy were developed to focus on the needs of these audiences. The first edition offered learning tools (e.g., review questions, discussion questions, additional readings) to assist readers in building on the text's basic terminology and concepts.

This second edition evolved from the first edition with a number of significant changes. The first and most visible change is the new title, *Introduction to Acute & Ambulatory Care Pharmacy Practice*. This new title explicitly acknowledges the growing importance of ambulatory care practice in health-system settings and is in line with the direction of ASHP.

PREFACE

In addition to the new title, the second edition has two new chapters. The first, Providing Sustainable Pharmacy Services in Ambulatory Care, discusses how to make ambulatory pharmacy services financially sustainable by using new, innovative business models. The second new chapter, Career Options for Technicians in Hospitals and Health Systems, explores the evolving roles of pharmacy technicians and discusses career and training opportunities in acute and ambulatory settings. All of the remaining chapters have been updated with new content. Of note are the following:

- A discussion about the Affordable Care Act in Chapter 1: Introduction to Acute and Ambulatory Care Health-System Pharmacy Practice
- Further analysis of the history of institutional pharmacy in Chapter 2: Overview of the History of Hospital Pharmacy in the United States
- An explanation of Lean Management practices in Chapter 6: Medication Safety
- A description of 340B/contract pharmacy, billing, and financial compliance in Chapter 13: Basics of Financial Management and Cost Control
- Introduction of the topic of employee engagement in Chapter 18: Recruiting, Selecting, and Managing Pharmacy Personnel
- An extensive update of Chapter 19: Preparing for Careers in Hospitals and Health Systems

Approach and Organization

This text presents an overview of essential terms, concepts, and processes in acute and ambulatory care pharmacy practice in a concise, practical, and understandable way. Content comes from recognized topic experts. Emphasis is on explaining, developing comprehension, and encouraging application.

The book consists of 20 chapters divided into eight parts. Part I, *Introduction*, answers the question, “What Is Health-System Pharmacy Practice?” It provides an overview, describes its history, and discusses key legal and regulatory issues. Part II, *Managing Medication Use*, describes how the medication-use process is controlled through formularies, clinical pharmacy practice, and medication safety practices. Part III, *Managing Medication Distribution*, describes systems for managing the distribution of medications (including controlled substances) throughout health systems. Part IV, *Using Technology*, discusses the role of automation, technology, and information systems in health systems. Part V, *Financial Management*, reviews key management responsibilities of the pharmacy department including revenue generation, inventory control, budgeting, and cost control. Part VI, *Sterile Product Preparation and Administration*, discusses key systems, practices, and terms in preparing and administering sterile products. Part VII, *Managing People*, addresses leadership and human resources management in health systems. Finally, Part VIII, *Careers in Health-System Pharmacy Practice*, discusses different training options for careers in health systems.

Prior knowledge of health-system practice is not necessary to use this text, because it is written in an easy-to-read style and provides definitions for unfamiliar vocabulary. Some of the major highlights of this book include:

- Learning objectives for each chapter
- Key terms highlighted and defined within chapters
- Key points highlighted and then explained by answering “so what?”
- Graphics and visual aids used throughout to illustrate key concepts
- Review questions provided at the end of each chapter for self-assessment
- Discussion questions provided in each chapter to initiate dialogue and debate

PREFACE

Intended Readers

This book is written for anyone interested in health-system pharmacy practice, especially students in PharmD and pharmacy technician programs. This book provides a foundation for introductory and advanced pharmacy practice experiences (APPEs) and on-the-job training in hospitals and health systems. Mastery of the book's terms and concepts will be particularly useful for students who plan to seek residencies.

The book can also be useful for students who plan to practice in community settings by helping them understand how health systems work. Not all community pharmacists understand health-system practice, although a general understanding of those systems can be valuable when interacting with pharmacists in them. Interactions often occur as patients move in and out of hospitals and other settings. Greater contact and understanding will also be needed across practice settings if integrated therapeutic interventions such as medication therapy management and specialty medicine are going to succeed in achieving positive patient outcomes.

Practicing pharmacists who read this book can gain insight into health-system practice. Non-health-system pharmacists working in community settings or other jobs will learn about the various financial, clinical, technological, and distributional systems in healthcare institutions. This can be especially useful for individuals seeking new career opportunities.

For Educators

This book can be used as the core text around which an elective or required course in health-system pharmacy practice can be built. It can also serve as a text for the integration of health-system pharmacy across the curriculum.

For a standalone elective or required course, educators can build learning experiences around individual chapters. The chapters can form the backbone of the course. Chapters can be supplemented with presentations by practitioners, classroom assignments, and active learning projects. A textbook would also help guide the presentations of different faculty involved in team-taught courses. For instance, Part I, *Introduction*, can be used to provide an overview of health systems and pharmacy practice within them. Faculty and guest speakers can describe common types of health-system settings and the types of patients treated in each as well as the pharmacist's roles and models of practice, the history of hospital pharmacy, and the various accreditation, regulation, practice standards, and policies and procedures influencing practice. Clarification of concepts within the related chapters can occur, and problem-based learning activities can be used to apply and synthesize ideas covered in the book and class.

Use of the text could also occur across the curriculum as part of an integrated, multidisciplinary education. This could be accomplished by mapping health-system pharmacy topics across curriculum, identifying the desired learning objectives for various courses, and matching book chapters to the learning objectives. For instance, chapters from the *Managing Medication Use* and *Managing Medication Distribution* sections of the book could be assigned as part of hospital introductory pharmacy practice experiences (IPPEs). Part VI, *Sterile Product Preparation and Administration*, could accompany laboratory classes that teach compounding of intravenous solutions. Financial management could be part of a pharmacy management course, while careers in health-system pharmacy practice could be part of career training. Students who complete all of the text's learning objectives would have much richer APPEs.

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CHAPTER 1

Introduction to Acute and Ambulatory Care Health-System Pharmacy Practice

Douglas J. Scheckelhoff and Kasey K. Thompson

LEARNING OBJECTIVES

After completing this chapter, readers should be able to:

1. Describe the most common types of acute and ambulatory health-system settings and the types of patients treated in each.
2. Describe the pharmacist's role in the medication-use process and specifically how pharmacists improve outcomes, reduce cost, and improve safety.
3. Contrast the pharmacist's role in acute and ambulatory settings.
4. Identify the four primary practice models seen in acute and ambulatory care health-system settings.
5. List the types of automation and technology common in today's health systems used to improve safety and efficiency of medication use.
6. List the other disciplines usually present when providing interdisciplinary team-based care.

provide more timely care, prevent duplication, and reduce cost.

- **Accreditation:** Determination by an accrediting body that an eligible healthcare organization complies with the accrediting body's applicable standards.
- **Health-system pharmacy practice:** Practice that includes the provision of distributional and clinical pharmacy services at a broad range of health-system settings including hospitals, ambulatory clinics, ACOs, patient-centered medical homes, long-term care, hospice, home infusion, specialty pharmacy, and correctional facilities.
- **Integrated health systems:** Systems that integrate all care under the umbrella of a central organization and often include inpatient/acute care, primary care/ambulatory clinics care, long-term care, and home care settings.
- **Patient-centered medical home (PCMH):** A care delivery model designed to provide patient-centered care coordinated through a primary care physician, with better and more timely access to services that results in better overall quality outcomes.
- **Practice guidelines:** Tools that describe processes found by clinical trials or by consensus opinion of experts to be the most effective in evaluating and/or treating a patient who has a specific symptom, condition, or diagnosis, or that describe a specific procedure. Synonyms include clinical practice guideline, practice parameter, protocol, preferred practice pattern, and guideline.

KEY TERMS AND DEFINITIONS

- **Accountable care organization (ACO):** A collaboration of hospitals, doctors, and other providers who work together voluntarily with the purpose of providing better coordinated care for Medicare patients. The goal is to

- **Practice model:** The operational structure that defines how and where pharmacists practice including the type of drug distribution system used, the layout and design of the department, how pharmacists spend their time, practice functions, and practice priorities. The predominant practice models include the drug-distribution-centered model, the clinical-pharmacist-centered model, the patient-centered integrated model, and the comprehensive model.
- **Privileging:** The process by which an oversight body of a healthcare organization or other appropriate provider body, having reviewed an individual healthcare provider's credentials and performance and found them satisfactory, authorizes that individual to perform a specific scope of patient care services within that setting.
- **Regulation:** Governmental order having the force of law.



INTRODUCTION

This chapter describes the unique and diverse practice of pharmacy in acute and ambulatory settings, with an emphasis on hospitals and integrated health systems. The purpose of this chapter is to introduce the concept of health-system pharmacy practice and key issues that will be discussed throughout this book.

WHAT IS HEALTH-SYSTEM PHARMACY PRACTICE?

Health-system pharmacy practice is the provision of distributional and clinical pharmacy services at a broad range of health-system settings including hospitals, **accountable care organizations (ACOs)**, **patient-centered medical homes (PCMHs)**, ambulatory clinics, long-term care, hospice, home infusion, specialty pharmacy, and correctional facilities. Typically, the institutions that pharmacists serve are linked together formally or informally into integrated health systems. As the term implies, **integrated health systems** blend all care under the umbrella of a central organization and often include inpatient/acute care, primary care/outpatient care, long-term care, and home care.

Health systems are a collection of organizations and institutions whose mission is to positively impact health outcomes. Although health systems may be made up of independent entities, they are systems because the entities are interdependent and unified. The integrated model creates the potential to provide enhanced levels of patient care continuity through access to medical records and patient care providers. At the completion of this chapter, the student will have a general understanding of the unique attributes that comprise the practice of pharmacy in hospitals and health systems, including the various factors that influence practice in these settings.

TYPES OF HOSPITALS

At one time, **health-system pharmacy practice** referred almost exclusively to service in hospital pharmacies; hospitals are still the biggest component of health-system practice. There are approximately 5,600 hospitals in the United States.¹

Hospitals traditionally employ a team of highly skilled nurses, physicians, pharmacists, and other healthcare practitioners to provide the required care and specialized services for acutely ill patients who require constant care. Hospitals are often differentiated by factors such as location, size, and specialization. Location-related factors can include whether a hospital is situated in a large urban area or small rural setting. Hospitals may be located in a single building or spread across a campus complex. Some hospitals have a distinct mission to educate and train healthcare professionals. These hospitals are termed *university teach-*

ing hospitals. Other hospitals emphasize distinct specialties such as cardiac surgery and oncology. The following are some common labels assigned to hospitals:

- **Community hospital** — Community hospitals are what most people think of when they hear the term *hospital*. They are the most common type and are designed to deal with an assortment of diseases and injuries. Community hospitals typically have emergency services for treating trauma and other imminent threats to health. They also have inpatients that need surgical, intensive care, obstetrics, long-term care, medical, and other services to treat a broad group of medical conditions.
- **Specialized hospital** — Specialized hospitals serve the needs of patients suffering from some particular disease (e.g., cancer, psychiatric illness), or affecting a specific organ system (e.g., eyes, lungs) or type of patient (e.g., children, seniors).
- **Teaching hospital** — Teaching hospitals have two missions—serving patients' needs and training future healthcare professionals. Teaching hospitals often have some association with medical schools and sometimes conduct medical research.
- **For-profit hospital** — For-profit hospitals are differentiated from nonprofit hospitals by their ownership. For-profit hospitals are owned by corporations or groups of private investors. They differ from nonprofit hospitals, which do not seek a return on investment for owners. Nonprofit hospitals often operate under religious, volunteer (e.g., Shriners), community, or other voluntary patronages. Any additional revenue generated after expenses is put back into the hospital.
- **Government hospitals** — These hospitals are owned or heavily supported by federal, state, county, or other governmental entities such as the Veterans Administration, U.S. Public Health Service (e.g., Bureau of Prisons, Indian Health Service), and the Armed Services (e.g., Army, Air Force, Navy). Various states, counties, and cities have hospitals for underserved populations such as indigent and psychiatric patients.
- **Multihospital system** — A multihospital system is formed when a central organization owns, leases, sponsors, or contract manages two or more hospitals. Over 60% of hospitals are part of multihospital systems.

KEY POINT . . .

There are approximately 5,600 hospitals in the United States.

. . . SO WHAT?

Hospitals exist in almost any location in the country—each employing pharmacists. Opportunities in health-system pharmacy practice are everywhere.

PHARMACY'S ROLES IN THE MEDICATION-USE PROCESS

The role of pharmacists is to lead and influence the safety and quality of all aspects of the medication-use process. This means that pharmacists should be involved in controlling or influencing any step of the medication-use process that can impact patient health outcomes or costs. Pharmacists have important direct or indirect roles in prescribing, transcribing, dispensing, administration, monitoring, and modifying as well as discontinuing therapy.

Prescribing

The prescribing of medications is often viewed as something that only physicians are authorized to do. The reality is that many other healthcare professionals are authorized

to prescribe by state law (e.g., dentists, nurse practitioners, optometrists, podiatrists) or through a formalized process in hospitals known as **privileging**. “Privileging is the process by which a health-care organization, having reviewed an individual healthcare provider’s credentials and performance and found them satisfactory, authorizes that individual to perform a specific scope of patient care services within that organization.”² Pharmacists who have prescribing privileges in hospitals are typically authorized to do so through the formalized privileging process.

A more common role for pharmacists beyond actually prescribing is the pharmacist’s duty to influence the prescribing of other health professionals. Pharmacists indirectly influence prescribing by acting as information resources about medications. They also provide feedback about the quality of prescribing and manage prescribing through the formulary system.

KEY POINT . . .

Pharmacists have important direct or indirect roles in prescribing, transcribing, dispensing, administration, monitoring, modifying, and discontinuing therapy.

. . . SO WHAT?

The pharmacist’s role in drug-use control does not end once a medication leaves the pharmacy. That role often includes helping others in their roles within the drug-use process. Indeed, a pharmacist’s greatest impact often lies in ensuring the quality of the physicians prescribing and the nurses administering the medications.

Transcribing

Transcribing is the process by which a prescriber’s written order is copied and either manually or electronically entered into pharmacy records. The transcribing process represents an opportunity for error, especially when done manually. Pharmacists must understand potential breakdowns in the transcribing process and help find ways to minimize errors. The problem of manual transcription has diminished greatly because of the movement toward computerized prescriber order entry, resulting in an electronic transmission of the order.³

Dispensing

Dispensing is the act of physically transferring the drug product following review and approval of the prescription to the area responsible for administering the medication to the patient. Dispensing is also an area where medication errors can occur including, but not limited to, wrong drug, wrong dose, or wrong dosage form errors.

Administration

In hospitals, nurses typically manage the medication administration to the patients. This phase of the medication-use process is the last step before patients are given their medications, and errors at this point cannot be corrected. When errors do occur in the medication-use process, studies have shown that upwards of 34% are in the administration phase.⁴ Nurses usually serve as the final check in the medication-use process. Pharmacists help improve the safety of medication administration by clearly labeling medications, using bar-coding systems and unit dose packaging, reducing the time and effort involved in accessing drugs (e.g., through the use of decentralized automated dispensing devices), and using technology that reduces administration errors (e.g., smart infusion pumps).

Monitoring

Monitoring the patient's response to the medication is a critical phase where pharmacists play a vital role. Monitoring includes reviewing laboratory values, which are correlated with the expected medication-therapy outcomes as well as other objective and subjective factors that indicate whether the therapy is effective, or may be having a toxic effect.

Modifying and Discontinuing

Modifying drug therapy occurs when a dosage change is required, or when one therapy is discontinued and a new therapy is initiated based on the patient's clinical response to the drug.

PRACTICE MODELS

Health-system pharmacists comprise their roles in practice models. A **practice model** can be defined as the

operational structure that defines how and where pharmacists practice, including the type of drug distribution system used, the layout and design of the department, how pharmacists spend their time, practice functions, and practice priorities. The practice model is probably the most important factor determining the role and effectiveness of the pharmacy department. It sets the stage and defines the roles.⁵

The term *practice model* describes how pharmacists, pharmacy technicians, and automation interrelate to provide pharmacy services. Practice models used vary based on the hospital type (e.g., community versus academic), institution size (e.g., large versus small), patient population (e.g., chronic versus critical care), or philosophy of how pharmacy services should be delivered. There are four major pharmacy practice models⁶:

- **Drug-distribution-centered model** — In this model, pharmacists primarily distribute drugs and process new medication orders. The pharmacist's role is reactive, in that he or she responds to requests of physicians and nurses but rarely initiates major changes in therapy. In this model, the pharmacist is not actively involved with the healthcare team or in development of therapeutic plans for the patient. Consequently, pharmacists are not accountable for the health outcomes of patients and exert little leadership in influencing the medication-use process.
- **Clinical-pharmacist-centered model** — There are two types of pharmacists in this model who serve separate roles in the medication-use process. *Clinical pharmacists* work with medical teams on the nursing units to provide services. In its extreme form, clinical pharmacists in this model are not accountable for drug distribution or delivery systems. Their primary responsibility is assisting physicians and other health professionals in avoiding and solving clinical problems exclusive of the distribution process. Drug distribution is managed by a second type of pharmacist—the *distribution pharmacist*. These pharmacists spend most of their time managing technicians in the dispensing and distribution of medications. Limited collaboration occurs between clinical and distributive pharmacists in the extreme of this model, so these pharmacists are selectively accountable for the medication-use process.
- **Patient-centered integrated model** — In this model, all pharmacists in the department accept responsibility for all elements of the medication-use process and, therefore, spend their time on both clinical and distributive functions. Pharmacists' roles in drug distribution are often limited, because many distribution tasks

are delegated to well-trained pharmacy technicians. Therefore, pharmacists are able to expand their clinical roles to more active engagement in medication selection and drug use as part of an interdisciplinary team. In this model, pharmacists exhibit a high degree of ownership of and accountability for the entire medication-use process.

- **Comprehensive model** — A fourth model is emerging in practice, which can be called the comprehensive model. It combines elements of the clinical-pharmacist-centered model and the patient-centered integrated model. The comprehensive model includes a majority of pharmacists spending their time on both clinical and distributive functions, but it also has clinical pharmacy specialists assigned to specific locations or disease states. This way, the benefits of both models is realized. The resource requirements of this model are such that it is often seen only in larger academic settings.

The models above are generalizations of what might be seen in practice, but they describe the tension between clinical and distributional roles of pharmacists. The degree to which a health-system pharmacy resembles any model depends on a variety of factors including its leadership; the relationships it develops with medicine, nursing, and the hospital administration; its involvement with colleges of pharmacy; the drug distribution model; variations in regional practice and work force; the presence or absence of pharmacy residency training programs; and department culture (e.g., staff members' willingness to accept responsibility for patient outcomes).⁶

The culture of the department influences the success of any particular practice model. The individuals who make up a pharmacy department will ultimately determine the delivery of services. Indeed, practice models must be understood and accepted by everyone within the organization. Pharmacists, technicians, and other individuals must appreciate how their individual efforts contribute to the department's mission. Unless the members develop a common vision, they will not work well as a team. And without teamwork, factions can develop within the pharmacy leading to "us-versus-them" attitudes.

Whatever the model of pharmacy practice, the following common features are likely to emerge as key⁷:

- Practice will need to be interdisciplinary and team based as will education and training of pharmacists.
- Medication preparation and distribution must be made more efficient with automation, centralization, and the use of trained technicians.
- Pharmacists' contributions to the medication-use process are going to increase in direct patient care and decrease in medication distribution.
- Health information technology will give pharmacists much greater ability to positively influence the medication-use process.
- Pharmacists will need to justify their value because allocation of healthcare resources will be heavily driven by metrics. The benefits of pharmacy services must be justified against their costs.

KEY POINT . . .

The culture of the department influences the success of any particular practice model.

. . . SO WHAT?

A culture where individuals are discouraged from trying new things often hinders the ability to advance the practice of pharmacy. In many instances, a change in culture is necessary for evolution to a new practice model.

- A pharmacotherapy plan should be developed for every patient. That plan should be comprehensive, multidisciplinary, accessible, and transferable to any provider or location. Primary responsibility for this plan should rest with the pharmacist.
- Pharmacists will need continuous training to practice pharmacy. Credentialing and privileging of pharmacists may be requirements for practice in general and specialty practice areas.
- Pharmacists in health systems will need to collaborate better with community pharmacists to coordinate care as patients transition from one practice setting to the next.

Although there are health-system pharmacists who have purely distributional responsibilities, most are increasingly involved in direct patient care. Direct patient care typically occurs with the pharmacist being part of an interdisciplinary patient care team, where diverse professionals are each responsible for patient care within their scope of practice and expertise. Teams typically include physicians, nurses, and pharmacists, and they may also include others such as respiratory therapists and social workers. These teams are synergistic, enabling the patient to benefit from their individual and collective skills in the most efficient way possible. The team concept has contributed to the pharmacist's clinical role through providing a portal for pharmacist recommendations on drug therapy and monitoring, and puts the pharmacist into daily contact with the patient. Because these models are becoming integral to experiential education models, most new graduates feel comfortable moving into these roles and often seek out these types of positions upon graduation.

KEY INDIVIDUALS

Importance of Pharmacy Leadership

Possessing good leadership skills and providing leadership is important for virtually all pharmacist roles, but it is especially crucial for those individuals responsible for the oversight of pharmacy services. This includes the primary pharmacist in charge and other pharmacy managers who have responsibility for specific aspects of pharmacy services.

The primary pharmacist in charge, usually referred to as the Director of Pharmacy, has ultimate responsibility and accountability for all aspects of the pharmacy service. This includes the safety of medication use, quality of drug information provided, financial budgeting and management, human resources, drug procurement, technology implementation, education and qualifications of their staff, regulatory compliance, and adherence to accreditation standards.^{8,9} The quality of services depends on strong leadership in these types of positions as well as the advancement of pharmacy practice.

Pharmacists

Pharmacists can fill a number of different roles in acute and ambulatory settings. The most traditional role is that of the dispensing pharmacist. These individuals are responsible for preparation of medications, either directly or through supervising the preparatory work of pharmacy technicians. Dispensing pharmacists play an important role in verifying that medications are prepared correctly and are dispensed accurately. But because of the increasing use of technicians, coupled with greater use of automation and technology and more dosage forms being commercially available, positions for dispensing pharmacists are declining in some institutions. While the dispensing pharmacist is less common, pharmacist oversight of the dispensing and preparation process remains critical. Fortunately, pharmacy education is preparing new pharmacy graduates to fulfill both dispensing and non-dispensing roles.

Clinical pharmacy practice is another role for pharmacists. Clinical pharmacists are likely to serve on interdisciplinary patient care teams and interact directly with patients. Clinical pharmacists usually have clinical pharmacy training and often have completed a pharmacy residency. Clinical pharmacists may be *generalists* and provide clinical pharmacy services to a wide range of patients, or they may be *specialists* who have a defined expertise in one or more areas (e.g., critical care, oncology). The prevalence of these clinical pharmacy roles continues to increase, and this trend will likely continue.

The most prevalent role in health-system practice is one where the pharmacist has both dispensing and clinical roles, usually referred to as an integrated practice.³ This type of role may involve the pharmacist spending a designated amount of time in each area (e.g., 1 month spent dispensing alternating with 1 month of clinical practice) or time split in a given day (e.g., mornings spent in patient care areas rounding and providing order review followed by afternoons in the pharmacy verifying technician-prepared medications). For the most part, these pharmacists are considered generalists in both dispensing and clinical activities.

Pharmacists in management usually serve as the supervisor for pharmacy activities or as the director for the pharmacy department. These roles require an understanding of the practice of pharmacy and how medications are used; a good knowledge of regulations and laws that govern pharmacy practice; and basic skills in human resource management, leadership, and budget management as well as ensuring quality of medication use. Good managers are especially important because the effectiveness of pharmacy services often depends on how well the department is managed and led.

Other pharmacist roles are evolving. Examples include pharmacists who are responsible for informatics, investigational drug services, research, sterile compounding, and emergency care.

Pharmacy Technicians

Pharmacy technicians continue to play an expanding role in virtually all practice models. Technicians have been integral in the purchasing, stocking, preparation, and compounding of medications. This has been and continues to be under the pharmacist's direct supervision. The scope of this role varies depending on the pharmacy technician's experience, training, and skills. The scope and responsibility often vary because technicians do not have consistent and standardized training requirements. Because technicians play an increasingly important role in drug preparation and dispensing, technician training standards are being established. This will allow greater responsibility to be transferred to pharmacy technicians because each will meet a defined training and certification standard.

Pharmacy technicians are also taking on new and expanded roles beyond preparation and dispensing. Some technicians are assuming roles that involve the maintenance of automated dispensing technology and other information technology systems. Others are

KEY POINT . . .

Pharmacy education is preparing new pharmacy graduates to fulfill both dispensing and non-dispensing roles.

. . . SO WHAT?

Educators still struggle with the decision about the exact role of pharmacists within health-system practice. Some advocate for the clinical-pharmacist-centered practice model, while other educators emphasize drug-distribution-centered or integrated practice models. This textbook takes the position that regardless of the preferred practice model, both dispensing and non-dispensing roles are important.

assuming roles that assist clinical pharmacists in the collection of laboratory values or other clinical data. In some organizations, pharmacy technicians are interviewing patients and reconciling medication regimens at home with those ordered during their hospital stay. Regardless of whether technicians are in traditional medication preparation roles or in one of these new capacities, their importance in freeing the pharmacist for more direct patient care responsibilities is increasing, and so is the need for training and certification.

Importance of Automation and Technology

Automation and technology have been used in pharmacy for many years, but use has grown considerably in the past 10–15 years. Pharmacy automation serves to increase efficiency and accuracy of dispensing. Medication-related technology used outside of the pharmacy (e.g., bar-coded medication administration, smart pumps, computerized prescriber order entry) is usually focused on safety. Pharmacy automation is important to the practice model because utilization of many available technologies can influence what the pharmacist and pharmacy technician do in support of medication dispensing. Full use of automation can redirect staff time away from routine technical tasks and toward more direct patient care activities.

The most common type of pharmacy automation is the *unit-based dispensing cabinet*. These cabinet-based technologies are usually located strategically in the patient care area and contain compartments where individual medications are stored. The compartments open and give access only to authorized users of the medication. Usually this authorization is based on the computer in the cabinet verifying that the medication has been approved through an interface with the pharmacy computer system. These systems have been successful because they place medications much closer to the user, but still allow electronic verification that the medication and dose are correct for the patient. They also simplify billing and documentation of medication administration.

The second most common type of pharmacy automation is the *pharmacy robot*. These systems contain hundreds of bar-coded packages placed in designated spaces on long rods. The robot moves to the designated space, verifies that it is the correct medication using the bar code, and removes the number of doses needed. The robot is usually used to prepare a 24-hour supply of oral and prepackaged injectable medications. Using this technology greatly reduces the pharmacist and technician time needed to prepare and check medications.

Automation used in sterile compounding ranges from small pumps used to fill syringes and prepare parenteral nutrition solutions to large systems with robotic arms capable of preparing all types of sterile intravenous (IV) solutions and infusions. These systems improve the efficiency of sterile product preparation while improving the accuracy of the preparation and minimize potential contamination. Other systems help manage pharmacy IV workflow and verify accuracy through a bar-code scan and gravimetric means.

Many medication-related technologies are used outside of the pharmacy to improve safety. These systems have a direct impact on the pharmacy and require active involvement by the pharmacy in making sure that systems are designed and used optimally to realize their safety benefits. Examples of medication-related technologies include:

- Bar-coded medication administration (BCMA) systems (see Chapter 9 for more information on BCMA), requiring pharmacy involvement in ensuring that drug packages have appropriate, readable bar codes and that information systems capture and document information.
- Computerized provider order entry (CPOE) systems (see Chapter 10 for more information on CPOE) require an interface or integration with pharmacy information systems so that medication ordering information is able to transfer between the

prescriber and the pharmacy. Standard order sets and verification mechanisms also require pharmacy involvement for these systems.

- Smart pumps are programmable pumps that allow the user to predefine minimum and maximum rates of administration, preventing errors where patients are under- or overdosed with medication. Pharmacy plays an important role in making sure that the limits contained in the drug library are clinically appropriate.

UNIQUE ASPECTS OF DIFFERENT PATIENT CARE AREAS

Inpatient Care

Most health-system care is provided to inpatients. Since healthcare reimbursement models changed in the 1980s, the shift has been to treat patients in the home or nonhospital setting whenever possible. These shifts have moved healthier patients to ambulatory clinic settings while focusing hospital care on treating only the sickest patients.

There are two primary categories of inpatient patient care areas: *critical care units* and *general care units*. Subsets exist for each, which varies by the types of patients treated within and reflecting the expertise of the staff assigned. Examples of critical care units include surgical, medical, neurosurgery, pediatrics, coronary care, neonatal, and burn. General care units include medical, surgical, pediatrics, cardiology, orthopedics, post-partum, obstetrics and gynecology, and oncology. The number and mix of units is usually determined by the size and location of the hospital, which determines the number and types of patients who are admitted.

The pharmacist's role in a critical care unit is different than other settings because the patients are of a higher acuity level, meaning that they have greater needs for care. Patients in critical care are, by definition, critically ill; therefore, their clinical status is constantly changing. They must be monitored closely, and their drug therapy is often changed or adjusted. Typically, these patients are on multiple IV medications, thereby creating a high potential for incompatibilities, drug interactions, and errors. These patients also may have declining organ function, such as kidneys or liver, which affects drug dosing. The pharmacist plays a critical role in making sure that patients are receiving the right drugs, in the dose that is appropriate for their condition, and without error. The pharmacist usually participates in medical rounds with the rest of the healthcare team, providing advice and information on drug therapy. After rounds, there is often follow up on questions and responses to new treatment needs that arise throughout the day. Numerous studies have documented the impact of having a pharmacist in the critical care unit on patient outcomes.¹⁰

The pharmacist's role in general inpatient care units is different from critical care patients primarily because the acuity of patients is less. Drug therapy is more likely to be stable and many times is a combination of oral and IV medications, depending on the patient's treatment regimen. The general inpatient care unit has unique issues related to medications, such as ensuring that the patients' orders on admission accurately reflects

KEY POINT . . .

There has been a shift to treat patients in the home or nonhospital setting whenever possible.

. . . SO WHAT?

Inpatient pharmacists now take care of sicker patients who require increasingly complex and intense services. Inpatient pharmacists require extensive training and expertise like that acquired from accredited residency programs.

those medications being taken at home (a process called *medication reconciliation*), making sure that discharge orders are appropriate, and ensuring that patients are able to continue their medications on arriving home. These handoffs on admission and discharge are important so that the patient has continuity of care. Depending on the type of hospital (some smaller and community-based hospitals do not use traditional medical rounds with a team), the pharmacist may attend medical rounds with a healthcare team.

Pharmacists also are responsible for the drug distribution to all inpatients, which is supported by pharmacy technicians and automation, with a goal of providing safe, efficient, and cost-effective drug therapy.

Ambulatory Clinics

Various ambulatory care settings are commonly associated with health systems. Increasingly, many of these clinics include one or more pharmacists as part of their care team. This is most common for patient populations where medication therapy is complex or requires special monitoring. Clinics may be general in nature (e.g., primary care, medication adherence) or specialized (e.g., anticoagulation, palliative care). In these settings, medication therapy is managed by a pharmacist and usually patients see the pharmacist one-on-one by appointment. Pharmacists have great potential to improve medication-therapy outcomes, reduce errors, and reduce readmissions in ambulatory clinic settings.

Other ambulatory settings are less traditional and can vary widely in the types of patients served and the nature of services provided. Pharmacists are increasingly working in emergency departments because of a growing recognition of the value they can provide in medication use. The pharmacist's role in the emergency department usually includes drug therapy consultation with providers, error prevention and patient safety, monitoring adherence to practice guidelines, medication counseling, reviewing patient profiles, and participating in resuscitation efforts.^{11,12}

Another unique ambulatory care setting includes home healthcare. Home healthcare services, specifically home infusion services, have evolved as a way for patients to be treated in a nonhospital setting, usually their home. These pharmacy services are unique in that they provide infusion therapy for both short- and long-term chronic conditions. Common therapies include antimicrobial therapy, pain management, parenteral nutrition, and chemotherapy administration. Because a nurse is not administering the drug or monitoring the patient, allowances for training, storage, labeling, administration, and disposal must all be taken into consideration. Pharmacists play an important role in making sure that patients receive their medications appropriately under these less controlled conditions.

Changes in healthcare delivery models and financing are translating into new and important roles for pharmacists in other ambulatory care settings as well. Many health systems are acquiring physician office practices to add to their patient base and to offer greater ambulatory care sites. Pharmacists often are assigned to these practices and function much as the pharmacists described in the clinic settings above. Some health systems are also forming ACOs, which also provide a new and unique opportunity for pharmacists to improve the use of medications and often reduce costs.

A highly visible ambulatory care service is the ambulatory dispensing pharmacy, similar to community pharmacies without general merchandise. Larger hospitals typically have at least one ambulatory dispensing pharmacy that caters to clinic patients, patients being discharged from inpatient settings, and patients with prescriptions written in emergency departments.

ACCREDITATION AND STANDARDS OF PRACTICE

A variety of requirements and guidance including, respectively, accreditation and practice standards govern health-system pharmacy practice. **Accreditation** is a voluntary process by which an outside accrediting body assesses the quality of hospital-provided care on a routine basis. Groups that accredit hospitals in the United States include The Joint Commission, American Osteopathic Association, and DNV LG Healthcare. Accreditation organizations are different from regulatory bodies in that their primary purpose is to assess and improve the quality of patient care (i.e., when they identify a quality-of-care problem, they work with the hospital to make improvements).

Accreditation organizations have no authority to impose fines or bring legal action. **Regulatory bodies** such as the U.S. Food and Drug Administration, Centers for Medicare & Medicaid Services, Drug Enforcement Administration, state and local departments of health, and state boards of pharmacy are law enforcement bodies whose purpose is public protection, and are therefore tasked with imposing fines and taking other legal actions.

Practice standards or **practice guidelines** are those practices that a profession develops and imposes on itself. Practice standards should be based on the best scientific evidence, and should ideally strive to surpass minimum requirements established by law or regulation. Although elements of practice standards may be adopted or adapted into law or regulation, they are still considered different from laws and regulations because they are developed by the profession that is engaged in the practice for which the standards are developed, they are voluntary, and they surpass minimums. ASHP has developed standards—termed *Best Practices*—for the practice of pharmacy in hospitals and health systems.¹³

The details of accreditation, regulation, and practice standards are beyond the scope of this chapter; they are discussed in greater detail in Chapter 3. The important thing to remember is hospitals and health systems are highly regulated organizations that can be subjected to voluntary accreditation and are always subjected to regulatory oversight.

KEY POINT . . .

The quality of pharmacy services depends on strong leadership.

. . . SO WHAT?

Good leadership can make the difference between excellent and deficient pharmaceutical care. Institutions need pharmacists to take both formal and informal leadership roles within hospitals and other practice settings.

HEALTHCARE DELIVERY SYSTEM

The model for providing and paying for healthcare in institutions and other settings is continually evolving. Models for payment are usually dictated by the payer, and therefore can have significant implications for how hospitals are structured and how they provide care. For example, because of the high cost of inpatient care, many payers have incentivized hospitals to discharge patients into ambulatory settings as soon as possible. The impact of this change has been a shift in focus toward more ambulatory care.

Recent and proposed legislation will continue to impact how healthcare is delivered and paid for.¹⁴ In addition to expanding healthcare insurance coverage, these laws have brought many changes to hospitals that care for Medicare and Medicaid patients, with a notable shift in emphasis away from simply paying for services to providing incentives for quality and improved patient outcomes. Examples of new provisions include ACOs,

value-based purchasing, PCMHs, reductions in payments for hospital-acquired infections, and unnecessary readmissions. These types of changes are causing health systems to reassess how and where care is provided and the need to respond with new strategies. A few examples of the pharmacists' response include adding emphasis and resources to discharging patients more effectively (with discharge prescription programs), reducing hospital-acquired infections (with antimicrobial stewardship programs), and reducing medication-related admissions and readmissions (with effective medication reconciliation). These new programs align well with the skill set of pharmacists and ultimately bring better care to the patient. There has also been a response in ambulatory care, with many more pharmacists seeing patients in clinics, providing services such as medication therapy management, anticoagulation therapy management, and pain management—all aimed at improving patient management through appropriate use of medicines.



SUMMARY

The practice of pharmacy in health-system settings is unique and diverse; it requires pharmacists to have skills and expertise beyond those generally gained through pharmacy education. However, the nature and diversity of the health-system pharmacy environment present opportunities for pharmacists to provide patient care services as integrated members of the healthcare team. Integrated health systems provide additional opportunities to create an interconnected continuum of care in which all healthcare providers have information about the patient from all other settings where care was provided. Having access to patient information throughout the continuum of care creates opportunities to streamline and improve care and minimizes the potential for medication errors and other adverse events.

The practice model in pharmacy continues to evolve, as do the skills required to manage complex medication therapies. Many changes have occurred over the past 20 years that have positioned pharmacists who work in hospital and health-system settings as the medication therapy and medication-use system experts. This recognition of the pharmacist as an integral member of the patient care team brings the pharmacy profession closer to a patient-centric practice model.

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CHAPTER REVIEW QUESTIONS

1. Which of the following are NOT steps in the medication-use process?

- a. Transcribing
- b. Diagnosis
- c. Monitoring
- d. Dispensing
- e. Prescribing

Answer: b. Diagnosis. Diagnosing illnesses and injuries is one of the primary tasks of physicians. It falls outside of the pharmacist's responsibility, although some pharmacists are involved in some diagnosis of minor illnesses as part of collaborative practice plans. The medication-use process describes all steps involved in the use of medications in inpatients including prescribing, transcribing, dispensing, administration, and monitoring. It is important that the pharmacist be involved in ensuring the safety and quality of each step.

2. **The pharmacy practice model is one where pharmacists are chiefly involved in clinical activities associated with medical teams on the nursing units.**
- a. True
 - b. False

Answer: b. False. There is no single pharmacy practice model. A practice model can be defined as the “operational structure that defines how and where pharmacists practice, including the type of drug distribution system used, the layout and design of the department, how pharmacists spend their time, practice functions, and practice priorities.” There are many practice models with the three predominant models consisting of the drug-distribution-centered model, the clinical-pharmacist-centered model, and the patient-centered integrated model.

3. **Which of the following key components influence the type of pharmacy practice model utilized in an institution?**
- a. The culture of the department
 - b. The pharmacists working in the pharmacy
 - c. The technicians
 - d. Availability of automation and technology
 - e. All of the above

Answer: e. All of the above. Many different factors influence the type of pharmacy practice model in an institution. One important factor is the culture of the department and vision for practice, including the pharmacist’s role in providing direct patient care versus distribution. Also, the role of pharmacy technicians in providing drug distribution is a key component. The use of automation and technology can impact the safety and efficiency of drug distribution and free up the pharmacist to provide direct patient care. The pharmacy’s commitment to team-based care can also be a factor in how the practice model is structured and how it functions.

4. **Regardless of the pharmacy practice model utilized in a hospital, which of the following will likely be true?**
- a. Pharmacists practice in an interdisciplinary manner as part of team-based care model.
 - b. Automation and technology are making distribution more efficient and safe for patients.
 - c. Pharmacy technicians will be utilized for more drug preparation and distribution activities, and pharmacists will spend more time in direct patient care.
 - d. All of the above

Answer: d. All of the above. All of these factors are considered to be common features of new and emerging pharmacy practice models.

5. **Describe the types of automation and technology commonly used in hospitals that support safe and effective medication use.**

Answer: Commonly used technologies include unit-based cabinets for medication dispensing, robotic dispensing systems, bar-coded medication administration, smart pumps, and CPOE.

6. **The pharmacist’s role in an inpatient critical care unit differs from a general inpatient care unit because the acuity level is higher in a critical care unit.**
- a. True
 - b. False

Answer: a. True. The pharmacist's role in a critical care unit is different than other settings because the patients are of a higher acuity level. Patients must be monitored closely, and their drug therapy is often changed or adjusted. The pharmacist plays a crucial role in making sure that patients are receiving the right drugs, in the dose that is appropriate for their condition, and without error. The pharmacist usually participates in medical rounds with the rest of the healthcare team, providing advice and information on drug therapy. After rounds, often follow-up on questions and response to new treatment needs arise throughout the day. The pharmacist's role in general inpatient care units is different from critical care patients primarily because the acuity of patients is less. Drug therapy is more likely to be stable, and many times it is a combination of oral and IV medications, depending on the patient's treatment regimen. The pharmacist may attend medical rounds with a healthcare team, depending on the nature of the hospital. (Some smaller and community-based hospitals do not use traditional medical rounds with a team.)

7. Which of the following are developed by the pharmacy profession and imposed on pharmacy professionals voluntarily?

- a. Regulations
- b. Policies and procedures
- c. Laws
- d. Practice standards
- e. None of the above

Answer: d. Practice standards. Practice standards or practice guidelines are those practices that a profession develops and imposes on itself. Practice standards should be based on the best scientific evidence and should ideally strive to surpass minimum requirements established by law or regulation. Although elements of practice standards may be adopted or adapted into law or regulation, they are still considered different from laws and regulations because they are developed by the profession that is engaged in the practice for which the standards are developed, they are voluntary, and they surpass minimums. ASHP has developed standards for the practice of pharmacy in hospitals and health systems known as *Best Practices*.

8. Pharmacy technicians primarily work in hospital settings and rarely are seen in other pharmacy settings.

- a. True
- b. False

Answer: b. False. Pharmacy technicians play an increasingly important role in virtually all pharmacy settings and practice models. Pharmacy technician training and certification continues to expand, resulting in a better trained and qualified member of the pharmacy workforce. Technicians routinely work in community and chain pharmacies, home health pharmacies, specialty pharmacies, and others. Technician roles also continue to expand in each of these settings, enabling the pharmacist to assume greater patient care responsibilities while technicians take on more preparation, distribution, and administrative roles.

9. The difference between a for-profit hospital and a nonprofit hospital is that nonprofit hospitals do not make any money.

- a. True
- b. False

Answer: b. False. Nonprofit hospitals bring in a lot of revenue, often exceeding their expenses by a healthy margin. In reality, for-profit hospitals are differentiated from

nonprofit hospitals by their ownership. Corporations or groups of private investors own for-profit hospitals. They differ from nonprofit hospitals, which do not seek a return on investment for owners. Nonprofit hospitals often operate under religious, volunteer, community, or other voluntary patronage. Any additional revenue generated after expenses is put back into the hospital.

10. What are some of the traditional and nontraditional roles of pharmacists in ambulatory care within health-system settings?

Answer: The most common, traditional role is within the outpatient dispensing pharmacy, similar to community pharmacies without general merchandise. However, a growing number of pharmacists practice in new areas. For example, pharmacists are increasingly working in emergency departments because of a growing recognition of the value they can provide in medication use. Another growing area of outpatient services includes ambulatory care clinics. Clinics may be general in nature (e.g., primary care, medication adherence) or specialized (e.g., anticoagulation, palliative care). Another unique outpatient care setting includes home healthcare. Home healthcare services, specifically home infusion services, have evolved as a way for patients to be treated in a nonhospital setting, usually their home.

CHAPTER DISCUSSION QUESTIONS

1. What new roles are emerging for pharmacists in ambulatory care settings? Will this trend continue?
2. How do the roles of pharmacists and technicians differ?
3. In the future, will pharmacy automation and technology replace the pharmacist or enhance their practice?
4. How will the day-to-day practice of pharmacists change in the future? What should pharmacists (or future pharmacists) do to prepare for the new reality?

Overview of the History of Hospital Pharmacy in the United States

William A. Zellmer

LEARNING OBJECTIVES

After completing this chapter, readers should be able to:

1. Describe how hospital pharmacy developed in the United States.
2. Analyze the forces that shaped the hospital pharmacy movement.
3. Use history to discuss challenges to the future of institutional practice.
4. Discuss how professional organizations such as ASHP advanced the practice of institutional pharmacy practice.
5. Define key terms associated with the history of hospital pharmacy.

and selects from among the drug products available those that are considered most useful in patient care. It is also the framework in which medication-use policies are established and implemented.

- **Full-time equivalent (FTE):** A method for standardizing the number of full- and part-time employees working in an institution. A full-time employee working a 40-hour week is equal to one full-time equivalent (FTE), and an employee who works for 20 hours per week is equal to 0.5 FTE.
- **Mirror to Hospital Pharmacy:** A publication documenting the state of pharmacy services in hospitals in the late 1950s.
- **Pharmacy and therapeutics (P&T) committee:** A committee of the medical staff of a hospital or health system with oversight for medication management. The committee establishes a formulary, assesses medication use, and makes recommendations on policies and procedures associated with medication management. It is made up of representatives of the medical staff, administration, pharmacy, nursing, and other parties interested in the medication-use process; a pharmacist often serves as secretary of the committee.
- **Practice standard:** An authoritative advisory document, issued by an expert body, which offers advice on the minimum requirements or optimal method for addressing an important issue or problem. It does not typically have the force of law.

KEY TERMS AND DEFINITIONS

- **ASHP Hilton Head conference:** A conference of hospital pharmacy leaders and pharmacy educators conducted in 1985 in Hilton Head, South Carolina, which emerged with the idea that hospital pharmacies should function as clinical departments with the mission of fostering the appropriate use of medicines.
- **Formulary:** A list of drugs approved for use within the hospital or health system by the pharmacy and therapeutics (P&T) committee.
- **Formulary system:** A structure whereby the medical staff of a hospital or health system, working through the P&T committee, evaluates, appraises,



INTRODUCTION

Hospitals and other institutional practice settings today offer immense opportunities for pharmacists who want to practice in an environment that draws on the full range of their professional education and training. It was not always so.

This chapter tells the story of how hospital pharmacy developed in this country, analyzes the forces that shaped the hospital pharmacy movement, and draws lessons from the changes in this area of pharmacy practice.

HOSPITAL PHARMACY'S NASCENCE^{a,1-4}

Pharmacists have been associated with hospitals as long as there have been hospitals in America. When the Pennsylvania Hospital (the first hospital in Colonial America) was established in 1752, Jonathan Roberts was appointed as its apothecary. At that time, medicine and pharmacy were commonly practiced together in the community, with drug preparation often the responsibility of a medical apprentice.⁵

However, hospital pharmacy practice in the United States never developed into a significant movement until the 1920s. Although there were important milestones before that era (including the pioneering hospital pharmacy practices of Charles Rice [1841–1901]⁶ [see **Figure 2-1**] and Martin Wilbert [1865–1916]⁷), many factors kept hospital pharmacy at the fringes of the broader development of pharmacy practice and pharmacy education.

For much of the nation's history, hospital pharmacists were rare because there were few hospitals. In 1800, with a population of 5 million, the nation had only two hospitals. Even by 1873, with a population of 43 million, the United States had only 178 hospitals with fewer than 50,000 beds.² This might have not been a bad thing, because hospitals were “places of dreaded impurity and exiled human wreckage,” and physicians seldom had anything to do with them.⁸ Hospitals played a small role in healthcare, and pharmacists played a very small role in hospitals.

1800s

In the early to mid-1800s, drug therapy consisted of strong cathartics, emetics, and diaphoretics. Clean air and good food rather than medicines were the treatments emphasized in hospitals. The medical elite avoided drug use or used newer alkaloidal drugs such as morphine, strychnine, and quinine. An organized pharmacy service was not seen as necessary in hospitals, except in the largest facilities. The situation changed somewhat during the Civil War when hospital directors sought out pharmacists for their experience in extemporaneous manufacturing and in purchasing medical goods.²

In the 1870s and 1880s, responding to the influx of immigrants, the number of hospitals in cities doubled. Most immigrants in this period were Roman Catholic, and they built Catholic hospitals. This was significant for two reasons—Catholic hospitals charged patients a small fee (which allowed services to be improved) and they were willing to train, or obtain training for, nuns in pharmacy (see **Figure 2-2**).⁹ This era of hospital expansion

^aAmerican Society of Health-System Pharmacists (ASHP) in conjunction with anniversaries of its 1942 founding published well-documented accounts of the development of hospital pharmacy practice in the United States. Particularly noteworthy are the “decennial issue” of the *Bulletin of the American Society of Hospital Pharmacists* and articles that marked ASHP's 50th anniversary.¹⁻³ Readers who have an interest in more detail are encouraged to seek out those references and others.⁴ This section of the chapter is based closely on reference 2.



FIGURE 2-1. Hospital Pharmacy Department, Bellevue Hospital, New York City, late 1800s.

The bulk medicine area, where medicines were packaged for use on the wards, at Bellevue Hospital, New York City, in the late 1800s. Standing on the right is Charles Rice, the eminent chief pharmacist at Bellevue, who headed three revisions of the *United States Pharmacopeia*.

Source: AJHP.

coincided with reforms in nursing, development of germ theories, and the rise of scientific medicine and surgery. The general adoption of aseptic surgery in the 1890s made the hospital the center of medical care. Advances in surgery led to growth of community hospitals, most of which were small and relied on community pharmacies to supply medicines.²

EARLY 1900s

By the early 20th century, hospitals had developed to the point of having more division of labor, more specialization in medical practice, a greater need for professional pharmaceutical services for handling complex therapies, and recognition that it was more economical to fill inpatient orders in-house. Hospital pharmacists retained the traditional role of compounding, which fostered a sense of camaraderie among them and an impetus to improve product quality and standardization. The advent of the hospital formulary concept persuaded many hospital leaders about the value of professional pharmaceutical services. An important reason for hiring a hospital pharmacist in the 1920s was Prohibition—alcohol was commonly prescribed, and a pharmacist was needed for both inventory control and to manufacture alcohol-containing preparations, which were expensive to obtain commercially.²

KEY POINT . . .

Catholic hospitals were important to the progress of hospital pharmacy because they charged patients a small fee (which allowed services to be improved), and they were willing to train, or obtain training for, nuns in pharmacy.

. . . SO WHAT?

It might surprise some students and young pharmacists of the critical importance of religious organizations in the progress of the pharmacy profession. Look at pictures of hospital pharmacy leaders in the 20th century, and it will be common to see nuns prominent among that group.



FIGURE 2-2. Sisters of Mercy in the pharmacy department of St. Francis Hospital in New York City during the mid-1950s.

Catholic nuns were instrumental in developing U.S. hospital pharmacy practice. In the late 1950s, more than half of the women who were chief pharmacists in hospitals were members of a religious order.

Source: From the Drug Topics Collection, Kremers Reference Files, American Institute of the History of Pharmacy.

By the 1930s, pharmacy-related issues in hospitals had coalesced to the point that the American Hospital Association (AHA) created a Committee on Pharmacy to analyze the problems and make recommendations. Hospital pharmacy leaders considered the 1937 report of that committee so seminal that even a decade later they saw value in republishing it.¹⁰ The committee's aim was to develop minimum standards for hospital pharmacy departments and to prepare a manual on pharmacy operations. The committee characterized pharmacy practices in hospitals at the time as "chaotic" and commented, "Few departments in hospital performance have been given less attention by and large than the hospital pharmacy." In the committee's view, "...any hospital larger than one hundred beds warrants the employment of a registered pharmacist.... Unregistered or incompetent service should not be countenanced, not only because of legal complications but to insure absolute safety to the patient."¹⁰ The proliferation of unapproved and proprietary drug products in hospitals was the target of the committee's extensive criticism.

KEY POINT ...

It was not until the 1930s that hospital leaders explicitly recognized the need for pharmacy services.

... SO WHAT?

Pharmacy may have a long history, but it was only about 80 years ago that hospital leaders recognized a need for pharmacists.

A 60-YEAR PERSPECTIVE

There is much that can be learned by comparing contemporary hospital pharmacy with practice of 60 years ago. Sixty years is a comprehensible period of time for most people and, in hospital pharmacy's case, the past six decades were a period of astonishing advancement.

Good data sources for making such a comparison are available. A major study of hospital pharmacy was conducted between 1957 and 1960—the Audit of Pharmaceutical Services in Hospitals—and published in a book, *Mirror to Hospital Pharmacy*, which remains a reference of monumental importance.^{11,12} Over the years, ASHP (American Society of Health-System Pharmacists and before 1995 known as the American Society of Hospital Pharmacists) has documented the progress of hospital pharmacy through its annual surveys of pharmacy practice in hospital settings, yielding contemporary data for comparison with figures from an earlier era. Five major themes emerge from an examination of changes over this period:

1. Hospitals have recognized universally that pharmacists must be in charge of drug product acquisition, distribution, and control.
2. Hospital pharmacy departments have assumed a major role in patient safety.
3. Hospital pharmacy departments have assumed a major role in promoting rational drug therapy.
4. Many hospital pharmacists have become patient care providers.
5. Hospital pharmacy departments have expanded their clinical activities to include patients in ambulatory care clinics.

To fully appreciate the changes in hospital pharmacy over the past 60 years or so, it is important to keep in mind what was happening in the United States as a whole. Since 1950, the U.S. population has more than doubled. Expenditures for healthcare services have grown from about 5% of gross domestic product to more than 17% (which has fostered an enduring stream of initiatives to curtail healthcare spending). Nonfederal, short-term general hospitals in 1950 numbered 5,031 and rose to a zenith of 5,979 in 1975; in 2012 the number stood at 5,010—16% fewer than the peak of 37 years earlier. On a per-capita basis, the number of inpatient hospital beds has declined 22% since 1950. Between 1965 and 2012, hospital outpatient visits increased nearly sevenfold.¹³⁻¹⁵

DRUG PRODUCT ACQUISITION, DISTRIBUTION, AND CONTROL

Sixty years ago, pharmaceutical services were still of marginal importance to hospitals. The 1949 hospital rating system of the American College of Surgeons had only three questions related to pharmacy, and responses to those questions contributed only 10% to the overall rating. Pharmacy was perceived as a complementary service department, not as an essential service.¹⁶

Fewer than half the hospital beds in the nation (47%) in the late 1950s were located in facilities that had the services of a full-time pharmacist.¹¹ Fewer than 4 out of 10 hospitals (39%) had the services of a pharmacist. Hospital size was an important determinant of the availability of a pharmacist. All larger short-term institutions—those with 300 beds or more—employed a

KEY POINT . . .

In the late 1950s, fewer than 4 out of 10 hospitals had the services of a full-time pharmacist.

. . . SO WHAT?

Many of today's pharmacists were born in hospitals without a pharmacist providing oversight for their care.

full-time pharmacist. Pharmacist employment declined sharply with decreasing hospital size—for hospitals of 200–299 beds, 96% employed pharmacists; 100–199 beds, 72%; 50–99 beds, 18%; and under 50 beds, 3.5%.

Today, the vast majority of U.S. hospitals have the services of one or more pharmacists. Important exceptions are small rural hospitals that sometimes still rely on the services of local community pharmacists. About 8% of the nation's hospitals have fewer than 25 beds; it is not known how many of them employ a pharmacist.

In 1957, the total number of hospital pharmacists was 4,850 full-time and about 1,000 part-time.¹¹ Today, there are about 60,000 **full-time equivalent (FTE)** pharmacists providing inpatient services in nonfederal short-term hospitals.¹⁷ (Hospitals employ approximately an equal number of pharmacy technicians.) About one-fourth of all actively practicing pharmacists in the United States work in hospitals.

Today's hospitals employ approximately 17 FTE pharmacists per 100 occupied beds.¹⁷ The comparable figure for 1957 was approximately 0.4 FTE pharmacists per 100 occupied beds. In other words, pharmacist staffing in hospitals is about 40 times more intensive today than it was 60 years ago. During the same interval, the intensity of hospital staffing as a whole increased approximately fivefold.^{14,18} Reflective of more intensified pharmacist staffing, about 40% of hospitals offer 24-hour inpatient pharmacy services.¹⁷

In the middle of the 20th century, nurses and community pharmacists—not hospital pharmacists—were responsible for hospital drug product acquisition, distribution, and control in many hospitals. The *Mirror to Hospital Pharmacy* estimated that 4,000 nurses were engaged in pharmacy work.

Two types of services—bulk compounding and sterile solution manufacturing—were a major element of the hospital pharmacists' professional identity in the 1950s (**Figure 2-3**). Hospital pharmacy leaders of the time cited the following factors in explaining the heavy involvement in manufacturing:

- The unsuitability of many commercially available dosage forms for hospital use
- The close relationship between physicians and pharmacists in hospitals
- The opportunity to serve a need of physicians and patients
- The opportunity to offer a professional service and build interprofessional relations¹⁰

In sharp contrast to 60 years ago, hospital pharmacists now prefer to purchase commercial products whenever they are available, in the interests of appropriate deployment of the workforce and of using products of standard commercial quality. Changes in the laws and regulations that govern drug product manufacturing and distribution, the development of a well-regulated generic pharmaceutical industry, and a shift in the perceived mission of pharmacy practice were among the factors that led to the relegation of manufacturing to hospital pharmacy's past.

In summary, from mid-20th century to today, hospital pharmacy in the United States moved from an optional service to an essential service. It used to be that the administrator, the physicians, and the nurses in many institutions, especially smaller facilities, believed

KEY POINT . . .

Today, approximately one-fourth of all actively practicing pharmacists in the United States work in hospitals.

. . . SO WHAT?

The public image of the pharmacist is one working in an independent or chain pharmacy in the community. The public is generally unaware of the large number of pharmacists providing innovative services in hospitals and other institutional settings.

that they could function adequately with a drug room controlled by nurses. Today it is beyond question by anyone in the hospital field that medications need to be controlled by a pharmacy department managed and staffed by qualified pharmacists supported by qualified pharmacy technicians. Moreover, as pharmacists have become firmly established in hospitals, they have been recognized for their expertise beyond drug acquisition, distribution, and control functions, which has led to greatly intensified pharmacy staffing. The growing opportunities in hospitals have attracted more practitioners to the field, which has made hospital practice a major sector of the profession.

KEY POINT . . .

From the mid-20th century to today, hospital pharmacy in the United States has moved from an optional service to an essential service.

. . . SO WHAT?

Over the years, pharmacists have identified opportunities in healthcare institutions and carved out roles in managing the medication-use process.

This has taken leadership, hard work, building strong professional relationships, and caring for the patient.

PATIENT SAFETY

A clarion call to professionalism in hospital pharmacy arose in the 1960s following studies on the incidence of medication errors in hospitals.¹⁹ Hospital pharmacists have made immense progress in this arena. Initially, that progress was gauged in terms of minimizing errors in dispensing and administration of medications, and it has evolved to also focus on improving prescribing and ensuring that the intended results from medication use are achieved.



FIGURE 2-3. Sterile Solution Laboratory, Cardinal Glennon Memorial Hospital for Children, St. Louis, Missouri, circa 1950s. Production of distilled water and the manufacture of large-volume sterile solutions were major pharmacy activities in medium and large hospitals in the 1950s and 1960s.

Source: ASHP Archives.

In 1957, drug products were distributed to hospital inpatients using floor stock or individual-patient prescription systems.¹¹ Authors of the *Mirror to Hospital Pharmacy* highlighted a critical limitation of medication systems of that era:

From the viewpoint of patient safety, one of the major advances in dispensing procedures would be the interpretation by the pharmacist of the physician's original ... order for the patient. In many hospitals, the pharmacist never sees the physician's original order. In cases where the physician does write an original prescription, he does so only for a limited number of drugs, the other drugs being stock items on the nursing units. In many cases the pharmacist receives only an order transcribed by a nurse or even more commonly by a lay person such as a ward clerk. As a result, errors made by the prescribing physician and errors made in transcribing his orders often go undetected, while the patient receives the wrong drug, the wrong dosage form, or wrong amount of the drug, or is given the drug by injection when oral administration was intended, and vice versa.^{11(p115)}

Studies documented important benefits to unit dose drug distribution, including greater nursing efficiency, better use of the pharmacist's talents, cost savings, and improved patient safety.^{20,21} The key elements of unit dose drug distribution, as the system has evolved from the original studies, are as follows:

1. The pharmacist receives the physician's original order or a direct copy of the order.
2. A pharmacist reviews the medication order before the first dose is dispensed.
3. Medications are contained in single-unit packaging that is labeled appropriately.
4. Medications are dispensed in as ready-to-administer form as possible.
5. Not more than a 24-hour supply of doses is delivered or available at the patient care area at any time.
6. A patient medication profile is concurrently maintained for each patient.²²

These fundamental precepts for safe drug distribution are met widely in U.S. hospitals today.¹⁷

Early unit dose drug distribution systems were very labor intensive, which stimulated an expansion in the use of pharmacy technicians (see **Figure 2-4**).²³ Working from pharmacist-reviewed handwritten physician orders, pharmacy staff added patients' medications (in unit dose packages) to mobile cabinets, which were then transported to patient care areas. Guided by a record of physicians' orders, nurses administered the medications and manually created a medication-administration record. Modern unit dose systems are highly automated, including the use of computerized physician order entry (with clinical decision support in most hospitals), application of machine-readable labeling of unit dose packages in dispensing and administration, robotic picking of doses for unit dose carts, or automated dispensing cabinets that are accessed by nurses. U.S. hospitals have exerted immense effort in applying computer technology to improve the safety of the medication-use process, stimulated in part by federal incentives.²⁴

The development of pharmacy-based intravenous (IV) admixture services, beginning in the 1960s, made a tremendous contribution to patient safety. Previously, nurses largely carried out this task in patient care areas.²⁵

Because of the advocacy of groups such as the National Academy of Medicine and various federal health agencies, improving patient safety is a major national priority.²⁶ Because that general interest in patient safety embraces medication-use safety, hospital pharmacists have cheered and felt "it's about time!" Breakthrough advances in medication-use safety will depend on further reengineering of the entire medication-use process, a shift toward a true team culture in providing care, and continued implementation of information technology.²⁷

PROMOTING RATIONAL DRUG USE

Edward Spease (dean of the School of Pharmacy at Western Reserve University) and Robert Porter (chief pharmacist at the University's hospitals) first promulgated the concept of a **pharmacy and therapeutics (P&T) committee** in U.S. hospitals as a formal mechanism for the pharmacy department and the medical staff to communicate on drug-use issues in 1936.^{11(p139)} Subsequently, the AHA and ASHP jointly developed guidance on the P&T committee and on the operation of a hospital formulary system. The **formulary system** is a method whereby the medical staff of a hospital, working through the P&T committee, evaluates and selects from among the drug products available those that are considered most useful in patient care. The formulary system is also the framework in which a hospital's medication-use policies are established and implemented.

A major imperative for the advocates of the formulary system in the mid-1900s was to manage the proliferation of drug products. In just one year, 1951, the number of market entries consisted of 330 new drug products, including 35 new drug entities, 74 duplications of drug entities, and 221 combination products.²⁸ In 1957, slightly more than half of all hospitals operated under the formulary system.¹¹ Today, essentially all hospitals do so.¹⁷ In 1957, 58% of hospitals had an active P&T committee, and a similar percentage of hospitals had a **formulary** or approved drug list. However, about one-fourth of the P&T committees were inactive.¹¹ Today, nearly all hospitals in the United States have an active P&T committee that meets an average of seven times a year.²⁹

In the late 1950s, the functions of P&T committees focused on very basic activities such as delegating to the chief pharmacist responsibility for preparing product specifications and selecting sources of supply (66% of committees) and approving drugs by nonproprietary name (50%).¹¹ In most hospitals today, under the guidance of the P&T committee, pharmacists are involved in selecting a patient's medication and its dosing following a physician's diagnosis, developing drug therapy guidelines, engaging in therapeutic interchange, and conducting medication-use evaluations.²⁹

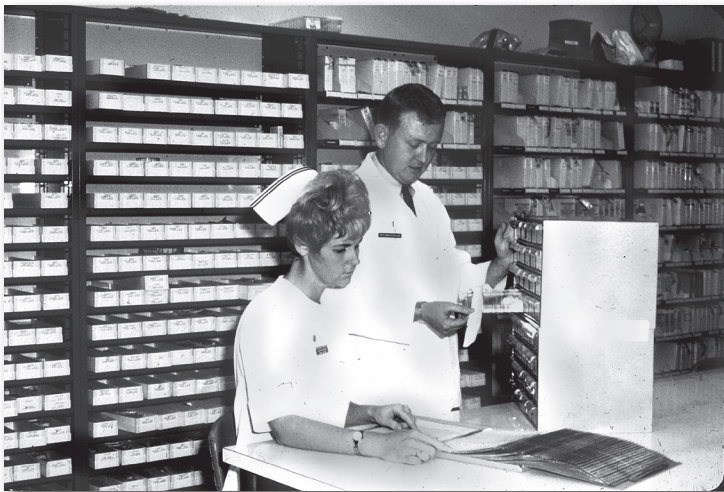


FIGURE 2-4. A sense of the labor- and paper-intensiveness of early unit dose drug distribution systems is conveyed in this image from the pharmacy department at Providence Hospital, Seattle, Washington, circa mid-1960s. Source: ASHP Archives, Herbert Flack Photograph Collection.

In summary, concepts first advanced in the 1930s regarding a formal linkage between the hospital pharmacy department and the medical staff with respect to drug-use policy have taken hold firmly. Hospital pharmacists are heavily engaged in helping the medical staff establish drug-use policies, in implementing those policies, in monitoring compliance with those policies, and in taking corrective action as needed. Additionally, there is a trend toward authorizing hospital pharmacists to select the medication regimen for a patient after a physician has made the diagnosis. The invention of the P&T committee and the formulary system has facilitated continuous advancement in the involvement of pharmacists in promoting rational drug use in hospitals.

KEY POINT . . .

The invention of the P&T committee and the hospital formulary system has facilitated the deep involvement of pharmacists in promoting rational drug use in hospitals.

. . . SO WHAT?

The pharmacist's role on the P&T committee has allowed pharmacists to build their professional standing in institutions. If they had never accepted leadership in establishing and maintaining these committees, their influence might have been diminished.

HOSPITAL PHARMACISTS AS PATIENT CARE PROVIDERS

U.S. hospital pharmacists have evolved markedly in their self-concept over the past 60 years. Thirty years ago, the traditional pharmacist mission still predominated, a mission that was captured in the words, *right drug, right patient, right time*, connoting a drug-product-handling function. *Right drug* in this context meant whatever the physician ordered. Today's philosophy about the mission of pharmacists focuses on whether patients are achieving the optimal outcomes from the use of medicines. An expression sometimes used to summarize this philosophy is, "The pharmacist is responsible for helping a patient make the best use of medicines."³⁰ The Joint Commission of Pharmacy Practitioners (JCPP), an alliance of all national pharmacist organizations, has expressed its consensus vision as follows: "Patients achieve optimal health and medication outcomes with pharmacists as essential and accountable providers within patient-centered, team-based healthcare."³¹ However expressed, the words reflect a profound paradigm shift with respect to the primary purpose of pharmacy practice.

The active consensus-building efforts by hospital pharmacy leaders stimulated the transformation of the hospital pharmacy department from a product orientation to a clinical orientation. One important example of such efforts was the **ASHP Hilton Head conference**.^{32,33}

The Hilton Head meeting was a consensus-seeking invitational conference conducted in 1985 in Hilton Head, South Carolina, officially designated as an invitational conference on Directions for Clinical Practice in Pharmacy. The purpose of the meeting was to assess the progress of hospital pharmacy departments in implementing clinical pharmacy. What emerged from the event was the idea that clinical pharmacy should not be thought of as something separate from pharmacy practice as a whole. Rather, hospital pharmacies should function as clinical departments with a mission of fostering the appropriate use of medicines. This was a very important idea because most hospital pharmacists thought in terms of adding discrete clinical services (e.g., pharmacokinetic monitoring) rather than conceptualizing the totality of the department's work as a clinical enterprise.

Working through its affiliated state societies, ASHP supported repetitions of the Hilton Head conference on a regional basis. ASHP leaders spoke at meetings around the country about the ideas of Hilton Head, and the *American Journal of Hospital Pharmacy* published numerous papers on the subject.

As a result, many individual pharmacy departments began to hold retreats of their staffs to reassess the fundamental mission of their work. It was common for departments to adopt mission statements that, for the first time, framed their work not in terms of drug distribution but in terms of achieving optimal patient outcomes from the use of medicines. They were supported by a growing body of scientific evidence, published in both the medical and pharmacy literature, about the positive outcomes achieved through pharmacist involvement in direct patient care.³⁴⁻³⁷

In more recent times, ASHP conducted important consensus-seeking events related to the pharmacy practice model in hospitals and in ambulatory care clinics.^{38,39} Both conferences issued bold recommendations on how to better align the capacity of pharmacists with the challenge of improving the responsible use of medicines. This challenge faces all sectors of pharmacy practice, and important work is being done on that broader front, as evidenced by JCPP's promulgation of a standard patient care process for pharmacists, which can be applied in all practice settings.⁴⁰ Expanded pharmacist engagement in patient care is a natural side benefit of healthcare leaders' efforts to improve team-based patient care.⁴¹

Some examples of hospital pharmacists' growing role as patient care providers include pharmacists routinely monitoring medication serum levels (95% of hospitals),⁴² pharmacists managing anticoagulation therapy (84% of hospitals),⁴³ pharmacists performing patient care functions in the emergency department (22% of hospitals),⁴³ and pharmacists routinely assigned to monitor a majority of patients at least 8 hours per day, 5 days per week (53% of hospitals).¹⁷

In summary, U.S. hospital pharmacists today are engaged in extensive clinical activity (often as full-fledged members of patient care teams), which is a major change from practice of 60 years ago. In many hospitals today, patients can be confident that their medication therapy is receiving close oversight by pharmacists.

KEY POINT . . .

After the Hilton Head conference, hospital pharmacy departments began to frame their work not in terms of drug distribution but in terms of achieving optimal patient outcomes from the use of medicines.

. . . SO WHAT?

The Hilton Head conference changed the practice model in institutions away from the process of drug distribution to a system of care that attempts to achieve optimal health outcomes. Many of the profession's initiatives in hospital practice have their origin in this conference.

HOSPITAL PHARMACISTS AND AMBULATORY CARE

Stimulated by various healthcare marketplace changes (including payment reform), most hospitals have become components of health systems that encompass primary care and specialty physician services as well as other facets of healthcare such as home care, long-term care, outpatient surgery, chemotherapy infusion, and urgent care. The trend in health

insurance coverage is to reward good patient outcomes and penalize poor outcomes, focusing on an entire episode of care, before, during, and after hospitalization. This gives hospitals a strong incentive to ensure that patients experience successful recovery after discharge from inpatient care. Because post-discharge healing and recovery often depend on how well medication therapy is handled, many hospitals are engaging pharmacists in medication adherence and monitoring programs for discharged patients.

A strong movement has emerged to place all facets of the pharmacy enterprise in a health system under consolidated leadership.^{44,45} In particular, pharmacy practice leaders who have such system-wide responsibility have moved assertively to establish pharmacists on the patient care teams of primary care and specialty clinics.⁴⁵ ASHP data indicate that about one-third of hospitals have pharmacists practicing in ambulatory care or primary care clinics.¹⁷

There is substantial evidence of patient benefit when pharmacists collaborate closely with primary care and chronic care providers, for example in optimizing the care of patients with diabetes, asthma, or cardiovascular disease.⁴⁶ Contemporary observers predict that hospital pharmacists will become increasingly active in rigorously coordinating post-acute care services⁴⁷ and that individual hospital pharmacists will have patient care responsibilities for both inpatients and outpatients.⁴⁸ Specialized pharmacy residency training⁴⁹ and specialty certification⁵⁰ are expanding the number of pharmacists who are qualified to contribute to the care of ambulatory patients.

In summary, after a half century of concentrating on the medication-related needs of inpatients, hospital pharmacists are increasingly expanding their focus to the care of ambulatory patients; it is likely that the historic lines separating acute care pharmacy practice from ambulatory care pharmacy practice will become blurred.

RECAP OF MAJOR THEMES

Thus, we have a picture of the thrust of major changes in hospital pharmacy over the past 60 years. The five major themes have been, *first*, the universal recognition by hospitals that pharmacists must be in charge of drug product acquisition, distribution, and control; *second*, hospital pharmacy departments have assumed a major role in patient safety; *third*, pharmacy departments have assumed a major role in promoting rational drug therapy; *fourth*, hospital pharmacists have become patient care providers; and, *finally*, pharmacy departments have expanded their focus to include patients in ambulatory care clinics. Taken together, these changes signify that pharmacy practice in U.S. hospitals over the past 60 years has become more intensive in its professional staffing, more directly focused on patient care, and more directly influential on the quality and outcome of patient care. Hospital pharmacy has been transformed from a marginal, optional activity into a vital profession contributing immensely to the health and well-being of patients and to the stability of the institutions that employ them.

EXPLAINING THE TRANSFORMATION

A combination of indirect and direct factors helps explain this transformation in hospital pharmacy. Indirect factors are those forces external to hospital pharmacy that fostered development of the field. These external factors include the following:

- Shift of national resources into healthcare, especially hospital care (stimulated immensely by implementation of Medicare in 1965 and expansion of other health insurance coverage)

- Expanded research on human health, which led to greater understanding of disease and development of targeted drug therapies
- Greater complexity and cost of drug therapy accompanied by sophisticated pharmaceutical product marketing
- Expanded information technology and automation
- A national commitment to improving healthcare quality and moderation of health-care expenditures

More important for this chapter's discussion are the internal factors within hospital pharmacy that precipitated the field's advancement. In this category, five points merit discussion:

1. Visionary leadership
2. Professional associations
3. Pharmacy education
4. Postgraduate residency education and training
5. Practice standards

VISIONARY LEADERSHIP

One cannot read the early literature of hospital pharmacy in the United States without being impressed by the clear articulation of an exciting, uplifting vision by that era's practice leaders. These views were being expressed at a time when pharmacy was a marginal profession in the United States; when most pharmacists were engaged primarily in retail, mercantile activities; when hospital pharmacy had little visibility and respect; and when hospital pharmacy was a refuge for pharmacists who preferred minimal interactions with the public. Out of this environment emerged a number of hospital pharmacists, many of them at university teaching hospitals, who expressed an inspiring vision about the development of hospital pharmacy and the role of hospital pharmacy in elevating the status of pharmacy as a whole.

These were leaders such as Arthur Purdum, Edward Spease, Harvey A. K. Whitney, and Donald E. Francke (to mention only a few) who were familiar with the history of pharmacy and had a sense of pharmacy's unfulfilled potential. Many of them had seen Western European pharmacy firsthand and decried the significant gap in professional status and scope of practice between that area of the world and the United States.

KEY POINT . . .

One cannot read the early literature of hospital pharmacy in the United States without being impressed by the clear articulation of an exciting, uplifting vision by that era's practice leaders.

. . . SO WHAT?

Hospital pharmacy has not always been the way it is now. It was built by pharmacists who led change in practice. In order for institutional pharmacy practice to thrive in the future, pharmacy students and newly graduated pharmacists will need to accept leadership positions vacated by pharmacy leaders who retire or leave the profession for other opportunities. They will need to provide a new vision for the profession for the 21st century.

A sense of these leaders' deep feelings is found in the following comment by Edward Spease, a retired pharmacy dean speaking in 1952 about his initial exploration of hospital pharmacy 40 years earlier:

I expected to see true professional pharmacy in hospitals and was much disappointed that it did not exist there. The more I observed and heard about the growing tendency towards commercialism in drugstores, the more I felt that if professional pharmacy was to exist, let alone grow to an ideal state, it would have to be in the hospital where the health professions were trained.... Good pharmacy is as important in hospitals away from teaching centers as it is in the teaching and research hospital. It can be developed to a high degree of perfection there, too, if the pharmacist can get the picture in his mind.⁵¹

The words, *if the pharmacist can get the picture in his mind*, reflect the goal of creating a new model for pharmacy practice in hospitals that transcended the marginal professionalism that prevailed in most community pharmacies. Spease and other hospital pharmacy leaders of the day were change agents who had a missionary zeal and were blessed with the ability to infect others with their passion.

It is noteworthy that the *Mirror to Hospital Pharmacy* framed the entire audit of the field in the context of professional advancement. Remarkably, more than 50 years after its publication, the *Mirror's* discussion of the essential characteristics of a profession^{11(pp35-40)} still has the capacity to inspire pharmacy students and practitioners.

PROFESSIONAL ASSOCIATIONS

ASHP, the national organization of hospital pharmacists, has had a profound effect on the advancement of the field. The visionary hospital pharmacists of the early 1900s focused much of their energies on the creation of an organizational structure for hospital pharmacy. One landmark event was the creation of the Hospital Pharmacy Association of Southern California in 1925. On a national level, organizational efforts were funneled through the American Pharmaceutical Association (APhA), the oldest national pharmacist organization in the country. For years, hospital pharmacists participated in various committee activities of APhA focused on their particular interest. Then, in 1936, a formal APhA subsection on hospital pharmacy was created. This modest achievement evolved to the creation of ASHP in 1942 as an independent organization affiliated with APhA.⁵²

There are two essential things that ASHP has done for the advancement of hospital pharmacy. One is to serve as a vehicle for the nurturing, expression, and actualization of the professional ideals and aspirations of hospital pharmacists. This was done through the pages of the *Bulletin of the American Society of Hospital Pharmacists* (which later became the *American Journal of Hospital Pharmacy*). In its early years, ASHP conducted a series of educational institutes that were very influential in enhancing knowledge and skills and in building esprit de corps among hospital pharmacists.⁵³ Also noteworthy, especially as the organization has grown in size and diversity, is ASHP's efforts to develop consensus about the direction of pharmacy practice.^{32,33,38,39,54}

The second essential act of ASHP has been its creations of resources to assist practitioners in fostering the development of hospital pharmacy practice. One example is the *AHFS Drug Information* reference book and database that are widely used independent sources of drug information in U.S. hospitals. ASHP publications and other activities such as the Midyear Clinical Meeting have produced a source of funds beyond membership dues that are used to develop a broad array of services to help members advance pharmacy practice.

The original objectives of ASHP were as follows:

- Establish minimum standards of pharmaceutical service in hospitals
- Ensure an adequate supply of qualified hospital pharmacists by providing standardized hospital pharmacy training for 4-year pharmacy graduates
- Arrange for interchange of information among hospital pharmacists
- Aid the medical profession in the economic and rational use of medicines

The core strengths of ASHP today are as follows:

- Practice standards and professional policy
- Advocacy (government affairs and public communications)
- Network of autonomous affiliated state societies
- Practitioner education
- Residency and technician training accreditation
- Drug information resources
- Publications and web-based resources
- Practitioner networking

One of the reasons for ASHP's success has been its clarity about objectives and its concentrated focus on a limited number of goals. It is a testament to the wisdom of ASHP's early leaders that the goals expressed in 1942 still serve to guide the organization, although different words are used today to express the same ideas, and some other points have been added. The organization continues as a powerful force in the ongoing efforts to align pharmacists with the needs that patients, health professionals, and administrators in hospitals have related to the appropriate use of medicines.

PHARMACY EDUCATION

There are three important points about the role of pharmacy education in transforming hospital pharmacy. *First*, as pharmacy education as a whole has been upgraded over the years, hospital pharmacy has benefited by gaining practitioners who are better educated and better prepared to meet the demands in hospital practice. *Second*, hospital pharmacy leaders have put considerable pressure on pharmacy educators to upgrade the pharmacy curriculum, to make it more consistent with the needs in hospital practice. This is significant because practice pressure to meet the demands in hospitals served to elevate education for all pharmacists. Also, beginning in the 1970s, corresponding with increased emphasis on clinical pharmacy in the curriculum, hospital pharmacies played a much larger role in pharmacy education as clerkship (experiential) rotation sites for pharmacy students. *Third*, in the early days of clinical education, faculty members from schools of pharmacy began establishing practice sites in hospitals, which often had a large impact on the nature of the hospital's pharmacy service.

Table 2-1 shows how the minimum requirements for pharmacy education have evolved over the years. It took a long time for pharmacy in the United States to settle on the PharmD as the sole degree for pharmacy practice. Many bitter fights—between educators, between practitioners, among educators and practitioners, and among educators and the retail employers of pharmacists—occurred over this issue. After the matter was settled, everyone has moved on with the intention of making the best application of the pharmacist's excellent education.⁵⁵

Over the past 30 years, pharmacy education in the United States has been transformed completely from teaching primarily about the science of drug products to teaching primarily about the science of drug therapy. Transformation of hospital pharmacy practice from a product orientation to a patient orientation was greatly stimulated by this change in education.

TABLE 2-1.
Evolution of Minimum Requirements for Pharmacist Education in the United States

Year	Minimum Requirement (Length of Curriculum and Degree Awarded)
1907	2 years (Graduate in Pharmacy)
1925	3 years (Graduate in Pharmacy or Pharmaceutical Chemist)
1932	4 years (BS or BS in Pharmacy)
1960	5 years (BS or BS in Pharmacy) ^a
2004	6 years (PharmD)

^aTransition period; some schools offered only the BS or the PharmD degree; many schools offered both degrees, with the PharmD considered an advanced degree.

POSTGRADUATE RESIDENCY EDUCATION AND TRAINING

Stemming from their concerns about the inadequacy of pharmacy education for hospital practice, early ASHP leaders advocated internships in hospitals and worked for years to establish standards for such training. This led to the concept of residency training in hospital pharmacy and a related ASHP accreditation program.^{53,56,57}

Early hospital pharmacy leaders noted the following imperatives for hospital pharmacy residency training^{11(pp157-167)}:

- Hospitals were expanding, thereby creating a growing unmet need for pharmacists who had been educated and trained in hospital pharmacy
- Pharmaceutical education was out of touch with the needs in hospital pharmacy
- The internship training required by state boards for licensure was not adequate preparation for a career in hospital pharmacy practice
- Hospital pharmacists required specialized training in manufacturing, sterile solutions, and pharmacy department administration
- Organized effort was needed to achieve improvements in hospital pharmacy internships or residencies

Tens of thousands of pharmacists in hospital pharmacy practice today have completed accredited residency training. These individuals have been trained as practice leaders and change agents. Early in their careers, they came to understand the complexity of hospital pharmacy, including inpatient operations, outpatient services, drug product technology and quality, and medication-use policy. Residency training is the height of mentorship in professionalism in American pharmacy. Residency training guides young pharmacists in developing a personal vision (along with the requisite knowledge, abilities, and attitudes) for dedicating their careers to helping the profession achieve its full potential.

PRACTICE STANDARDS

Numerous legal and quasi-legal requirements affect hospital pharmacy practice. On the legal end of the spectrum are various federal laws governing drug products and state practice acts governing how the pharmacist behaves and how pharmacies are operated. At the opposite end of the spectrum are voluntary practice standards promulgated by organizations such as ASHP.

A **practice standard** is an authoritative advisory document, issued by an expert body, offering advice on the minimum requirements or optimal method for addressing an important issue or problem. A practice standard does not generally have the force of law. Methods used to foster compliance with practice standards include education and peer pressure. ASHP's practice standards have been very important in elevating the scope and quality of hospital pharmacy practice in the United States.

The origins of hospital pharmacy practice standards go back to 1936 when the American College of Surgeons adopted the *Minimum Standard for Pharmacies in Hospitals*. This document was semi-dormant for a number of years, but it served as a rallying point for hospital pharmacists³ and revision and promulgation of the Standard became a priority for ASHP.⁵⁸ The revision pursued by ASHP in the 1940s specified the following minimum requirements:

- An organized pharmacy department under the direction of a professionally competent, legally qualified pharmacist
- Pharmacist authority to develop administrative policies for the department
- Development of professional policies for the department with the approval of the P&T committee
- Ample number of qualified personnel in the department
- Adequate facilities
- Expanded scope of pharmacist's responsibilities:
 - Maintain a drug information service
 - Nurse and physician teaching
 - File periodic progress reports with administrator
- P&T committee must establish a formulary

From this modest beginning, ASHP in 2016 had more than 100 practice standards (including some endorsed documents developed by others) that covered a wide range of philosophical and practical aspects of hospital pharmacy practice and several important areas of therapeutics.⁵⁹ ASHP actively updates existing standards and develops new documents to guide emerging issues in practice.

ASHP practice standards have been used effectively over the years as a lever for advancing the scope and quality of hospital pharmacy services. The standards have been used in the following ways:

- Requirements for pharmacy practice sites that conduct accredited residency programs
- Guidance to practice leaders who aspire to provide state-of-the-art pharmacy services
- Guidance to hospital accreditation organizations such as The Joint Commission in establishing requirements for the medication-use process
- Tools for pharmacy directors who are seeking administrative approval for practice changes
- Guidance to regulatory bodies and courts of law
- Guidance to curriculum committees of schools of pharmacy

SUMMARY OF INTERNAL FACTORS

In summary, five internal factors have played a major role in transforming U.S. hospital pharmacy over the past 60 years: (1) visionary leadership, (2) a strong professional society, (3) reforms in pharmacy education, (4) residency training, and (5) practice standards. The common element among these forces has been dissatisfaction with the status quo and a burning desire to bring hospital pharmacy in better alignment with the needs of patients and the needs of physicians, nurses, other health professionals, and administrators in hospitals related to the responsible use of medicines. These success factors are far more than historical curiosities; contemporary leaders of the field continue to be faithful to them, as reflected in the organizational activities and current literature of hospital and health-system pharmacy.



SUMMARY

From the author's perspective, colored to be sure by participation in the hospital pharmacy movement for many years, four tentative lessons may be drawn from the history of U.S. hospital pharmacy:

1. Fundamental change of complex endeavors requires leadership and time. Hospital pharmacists are sometimes frustrated by the slow pace of change. Wider study of history might help practitioners dispel that discouragement while learning to formulate more effective strategies for advancement.
2. It is important to engage as many practitioners as possible in assessing hospital pharmacy's problems and identifying solutions, so that a large number of individuals identify with the final plan and are committed to pursuing it.
3. It is critical to recognize and capitalize on changes in the environment that may make conditions more favorable to the advancement of hospital pharmacy. This requires curiosity about the world at large and the ability to spot and analyze relevant trends.
4. It is important to regularly and honestly assess progress and embark on a new approach if the existing plan for constructive change is not working or has run its course. This requires open-mindedness and a good sense of timing.

Today's challenges in hospital pharmacy are no more daunting than those that faced hospital pharmacy's leaders and innovators in the past. Fortunately, hospital pharmacy is imbued with a culture of taking stock, assessing the environment, setting goals, making and executing plans, measuring results, and refining plans. If hospital pharmacy sticks to this time-tested formula, it will continue to be a beacon for the profession as a whole.

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CHAPTER REVIEW QUESTIONS

1. When was the first hospital pharmacist employed in the United States?

- a. 1752
- b. 1813
- c. 1854
- d. 1895

Answer: a. 1752. In that year, Jonathan Roberts was appointed as the apothecary at the first hospital in Colonial America, the Pennsylvania Hospital.

2. Which of the following events furthered the progression of hospital pharmacy in the United States?

- a. An influx of immigrants in the late 1800s
- b. The Civil War
- c. Prohibition
- d. All of the above

Answer: d. All of the above. All of these events led to changes in hospital pharmacy. The influx of immigrants to cities increased the number of Catholic hospitals and nuns trained as pharmacists. The Civil War increased the demand for pharmacists who could provide compounding and distribution expertise. Prohibition required pharmacists to provide greater oversight of alcohol-containing medical preparations.

3. Hospital leaders explicitly recognized the need for pharmacist services in which of the following decades:

- a. 1920s
- b. 1930s
- c. 1940s
- d. 1950s

Answer: b. 1930s. In 1937, the American Hospital Association (AHA) created a Committee of Pharmacy, which found that pharmacy practice at that time was “chaotic” and that “...any hospital larger than one hundred beds warrants the employment of a registered pharmacist.”

4. The primary objective of hospital pharmacy practice today is to deliver to nurses the medications needed by patients, as prescribed by physicians.

- a. True
- b. False

Answer: b. False. While “delivering the right drug for the right patient at the right time” was a large focus of U.S. hospital pharmacists before the 1980s, today the dominant thrust of hospital pharmacy is to ensure responsible use of medicines, reflecting a vision that “patients achieve optimal health and medication outcomes with pharmacists as essential and accountable providers within patient-centered, team-based healthcare.”

5. The primary stimulus for the development of unit dose drug distribution systems was to reduce the cost of hospital personnel.

- a. True
- b. False

Answer: b. False. Early unit dose systems were, in fact, very labor intensive (and paper intensive), but they were advantageous because they reduced the incidence of medication errors. Modern unit dose systems are highly automated at all steps of the medication-use process including ordering, verifying, dispensing, and administering the medicine to a patient, with built-in safety checks all along the way.

6. Pharmacy and therapeutics (P&T) committees are a relatively recent phenomenon in institutional pharmacy.

- a. True
- b. False

Answer: b. False. The first documented report of a pharmacy and therapeutics (P&T) committee was in 1936.

7. Which of the following was not a factor in the original creation of postgraduate residency training in hospital pharmacy?

- a. Pharmacy educators' lack of attention to the needs in hospital pharmacy.
- b. Desire by pharmacists to earn a credential that would give them an edge in the job marketplace.
- c. Pre-licensure requirement for internship training did not meet the needs in hospital pharmacy.
- d. Expansion of the hospital field.

Answer: b. Although, today, many pharmacy graduates pursue residency training to improve their prospects for landing a rewarding position in pharmacy practice, the original imperative for creating residency programs related to (1) the growing need for skilled hospital pharmacists and (2) the dearth of opportunities for learning how to practice hospital pharmacy.

8. Hospital pharmacists have a significant impact on the clinical and scientific focus of curricula in U.S. pharmacy schools.

- a. True
- b. False

Answer: a. True. Hospital pharmacy leaders have exerted pressure on pharmacy schools to train students for the needs of hospital practice. Hospital pharmacists have also influenced education by engaging in clerkship rotations with pharmacy students and teaching students in the classroom.

9. _____ are advisory documents developed by pharmacists that offer advice on the minimum requirements or optimal method for addressing an important issue or problem in hospitals.

- a. Practice standards
- b. Regulations
- c. Laws
- d. Reports

Answer: a. Practice standards. A practice standard is an authoritative advisory document, issued by expert bodies within the profession, which offers advice on the minimum requirements or optimal method for addressing an important issue or problem. Practice standards do not generally have the force of law. They have been very important in elevating hospital pharmacy in the United States.

10. Which one of the following factors best explains why hospital pharmacists today are giving more attention to ambulatory care?

- a. Salary incentives for pharmacists
- b. Hospital accreditation requirements
- c. Healthcare reimbursement trends
- d. A decline in hospital admissions

Answer: c. Evolving methods of paying for healthcare include “bundled payments” for an episode of care (i.e., one fixed amount of payment for a combination of hospital inpatient treatment and post-discharge care) and financial penalties for early re-admission following hospital treatment. Under these methods of payment, appropriate or inappropriate use of medications after hospital discharge can have a big financial impact on the institution, which gives hospitals an incentive to engage pharmacists in post-discharge patient care.

CHAPTER DISCUSSION QUESTIONS

- 1. Speak to a hospital pharmacist who is about half-way through his or her career (i.e., graduating a minimum of 20 years ago). Identify all of the major advances that have occurred in institutional pharmacy practice (e.g., important drugs, medical conditions, technology) since that person has graduated. Now, try to project the changes that will occur in the next 20 years of pharmacy practice.
- 2. Discuss with a recent residency-trained hospital pharmacist why he or she pursued a residency. Think about the extent to which this individual’s response indicates (1) concern about competing effectively for career opportunities, (2) desire to prepare for a role in pharmacy practice leadership, and (3) commitment to improving patient care.
- 3. Pharmacy leaders argue that their profession can no longer be product-centered (i.e., medication-centered). Does this mean that pharmacists should move to relinquish their responsibilities in drug product acquisition and distribution?
- 4. Compare the current state of community pharmacy practice with hospital pharmacy practice. What lessons can community pharmacists learn from the history of hospital pharmacy?
- 5. Discuss with two or more of your peers the value, if any, of studying the history of U.S. hospital pharmacy. In addition to intellectual value, is there any practical value in understanding the history of hospital pharmacy? Can you identify any contemporary unsettled issues in hospital pharmacy whose resolution might be aided by an understanding of the issue’s related history?

Key Legal and Regulatory Issues in Health-System Pharmacy Practice

John P. Uselton and Lee B. Murdaugh

LEARNING OBJECTIVES

After completing this chapter, readers should be able to:

1. Explain the complementary roles of accreditation, regulation, practice standards, and health-system policies and procedures.
2. List key certifying and accrediting agencies of institutions and their purposes.
3. Describe key federal and state regulatory agencies of institutions.
4. Identify professional associations involved with health-system pharmacy practice issues.
5. Describe the role of health-system policies and procedures in health-system pharmacy practice.

KEY TERMS AND DEFINITIONS

A number of terms are closely associated with health-system accreditation and pharmacy guidelines. Many are defined in context in the chapter; others are defined here. Definitions of some terms vary or are evolving.

- **Accrediting body:** An organization or entity that establishes standards for accreditation and determines that a healthcare organization complies with the standards.
- **Center for Improvement in Healthcare Quality (CIHQ):** An accrediting organization for the operation of hospitals.
- **Certification:** Confirmation by an entity that an organization complies with the entity's predetermined standards.
- **Certifying body:** An organization or entity that establishes standards for certification and determines that a healthcare organization complies with the standards.
- **Compliance:** Meeting or adhering to the requirements of a standard, law, rule, or regulation.
- **Deemed status:** An accrediting organization approved by the Centers for Medicare & Medicaid Services (CMS) that is in compliance with the Medicare Conditions of Participation.
- **Domain:** The set on which a function is defined.
- **Electronic health record (EHR):** A digital version of a patient's paper medical chart. It provides real-time information instantly and securely to authorized users.
- **Guideline:** Voluntary guidance and direction to practitioners and other audiences based on consensus of professional judgment, expert opinion, and documented evidence. Guidelines are written to establish reasonable goals and to be progressive and challenging, yet attainable as "best practices" in applicable settings.
- **Healthcare Facilities Accreditation Program (HFAP):** The American Osteopathic Association's (AOA) accrediting organization for the operation of hospitals.
- **Hospital-acquired condition (HAC):** An adverse medical condition acquired by a patient during a hospitalization that was not present on admission to the hospital.

- **Hospital readmissions:** A situation where a patient is discharged from the hospital and is readmitted to the hospital for the same or related care within 30, 60, or 90 days. These readmissions may be used as a measurement of the quality of hospital care.
- **The Joint Commission:** The principal accrediting organization for the operation of hospitals and other healthcare organizations.
- **Law:** A legally binding requirement imposed by a legislative body (e.g., U.S. Congress).
- **National Integrated Accreditation for Healthcare Organizations (NIAHO®):** DNV-GL Healthcare’s accrediting organization for the operation of hospitals.
- **Performance improvement (PI):** The continuous measurement, analysis, and improvement of the performance of systems and processes to achieve desired outcomes.
- **Quality improvement:** A formal approach to the analysis of performance and the systematic approach to improve it.
- **Regulation:** Governmental order having the force of law.
- **Rule:** An authoritative recommendation meant to guide behaviors associated with specific, limited situations.
- **Standard:** “A principle of patient safety and quality of care that a well-run organization meets. A standard defines the performance expectations, structures, or processes that must be substantially in place in an organization to enhance the quality of care, treatment, or services.”¹ Standards often reflect best practices (i.e., recognized by a majority of professionals in a particular field).
- **Survey:** “A key component in the accreditation process, whereby a surveyor(s) conducts an on-site evaluation of an organization’s compliance with ... accreditation requirements.”²
- **Value-based purchasing (VBP):** A type of payment system that holds healthcare providers accountable for both the cost and quality of the care they provide. Payments are linked to improved performance by healthcare providers. VBP identifies and rewards the best-performing providers and attempts to reduce inappropriate, inefficient care.



INTRODUCTION

This chapter describes **standards** (including laws, rules, regulations, pharmacy professional standards, national codes and **guidelines**, and organization-specific requirements) that guide pharmacy practice in hospitals and health systems. Major entities that influence these standards are also identified and described. The information is an introductory overview, and individuals interested in more detail discussed in this chapter should visit each entity’s respective website.

Numerous accreditation and **certifying bodies**, federal and state government organizations, nongovernmental standards-setting bodies, pharmacy professional associations, and health-system entities direct health-system pharmacists and practice (**Figure 3-1**). Some influence through their formal legal authority and ability to punish offenders with fines and imprisonment, while others influence through persuasion and the exertion of peer and consumer pressure. Influence comes from external entities (e.g., U.S. Food and Drug Administration [FDA], **The Joint Commission**), the profession (e.g., ASHP), or the provider institution itself (e.g., pharmacy department). All health-system pharmacists should have a working knowledge of various bodies that influence how they practice.

INFLUENCE BY EXTERNAL BODIES

Health-system pharmacy practice is highly regulated by accrediting bodies, governmental agencies, professional organizations, and other standard-setting entities external to the institution in which pharmacists practice. They hold pharmacists accountable for maintaining minimum standards of practice.

HEALTH-SYSTEM CERTIFICATION AND ACCREDITATION PROGRAMS

Healthcare organizations obtain certification to meet the terms of participation in governmental (e.g., Medicare, Medicaid) or private (e.g., Kaiser) reimbursement programs. For instance, the Centers for Medicare & Medicaid Services (CMS) must certify institutions to participate in the federal Medicare program. CMS is a federal agency that administers health-related programs such as Medicare and works in partnership with states to administer Medicaid, the Children's Health Insurance Program (CHIP), and the Health Insurance Portability and Accountability Act (HIPAA).³ CMS maintains oversight

KEY POINT ...

Some entities influence pharmacists through their formal legal authority, while others influence through persuasion and the exertion of peer and consumer pressure.

... SO WHAT?

Many of the rules and standards influencing pharmacy practice have been established within the profession by pharmacists, not imposed by external regulatory bodies. Pharmacists follow these rules and standards because the profession agrees that they are in the best interest of our patients and the public.



FIGURE 3-1. Numerous demands are placed on pharmacists by entities internal and external to the institution where they practice.
Source: D. A. Holdford

of the **survey** and **certification** of “acute and continuing care providers (e.g., hospitals, nursing homes, home health agencies [HHAs], end-stage renal disease [ESRD] facilities, hospices, and other facilities serving Medicare and Medicaid beneficiaries).”⁴ CMS develops Conditions of Participation (CoPs) that healthcare organizations must meet to participate in the Medicare and Medicaid programs. Each CoP consists of one or more standards that define the requirements for compliance. These standards are used to improve quality and protect the health and safety of beneficiaries.⁵

Accreditation acknowledges that a hospital or other healthcare organization has met or exceeded the requirements of an **accrediting body** (e.g., The Joint Commission, the **Healthcare Facilities Accreditation Program [HFAP]**, the **National Integrated Accreditation for Healthcare Organizations [NIAHO®]**, the **Center for Improvement in Healthcare Quality [CIHQ]**). Healthcare organizations stress the importance of maintaining their accredited status for several reasons. Loss of accreditation can severely affect an organization’s prestige and make it difficult to attract qualified staff. Achieving accreditation in many states is helpful for state licensure and may exempt accredited organizations from inspections. Accreditation standards sometimes become the expected legal standards of care, and failure to comply might present legal difficulties for an organization. It also affects an institution’s ability to receive funding from healthcare insurers.

The standards take into consideration that healthcare organizations are subject to state and federal laws and undergo substantial state inspection through licensure programs (e.g., hospital, pharmacy, fire and safety, health department). Therefore, CMS standards encourage practices in accordance with generally recognized principles and avoid conflict with state and federal laws, state licensure requirements, and Joint Commission, HFAP, NIAHO, and CIHQ standards. Although CMS conditions and standards are uniform throughout the country, interpretation and stringency of application vary considerably from state to state or between regions. However, one is typically in **compliance** if state board of pharmacy rules and regulations and standards of an accrediting body are met. CMS confers **deemed status** on a healthcare organization when that organization is judged or determined to be in compliance with relevant Medicare requirements. An organization is in compliance when it has been accredited by an “organization whose standards and survey process are determined by CMS to be equivalent to those of the Medicare program or other federal laws.”⁶ Joint Commission accreditation, HFAP accreditation, NIAHO accreditation, CIHQ accreditation, or CMS certification qualifies a healthcare organization to participate in Medicare programs.

The Joint Commission (formerly known as the Joint Commission on Accreditation of Healthcare Organizations) is “an independent, not-for-profit organization dedicated to improving the safety and quality of healthcare” in organized healthcare settings. Founded

KEY POINT . . .

CMS certifies. The Joint Commission, HFAP, NIAHO, and CIHQ accredit.

. . . SO WHAT?

CMS decides the standards needed for participating in the Medicare and Medicaid programs—standards followed by private insurers and other payers. Thus, CMS determines the quality standards needed to receive compensation for a major portion of the healthcare market. Compliance with these standards is determined by accrediting agencies like The Joint Commission, HFAP, NIAHO, and CIHQ. Recommendations by any of these nongovernmental agencies should be seen as having the support of CMS and the federal government.

in 1951, its members represent the American College of Physicians, American College of Surgeons, American Dental Association, American Hospital Association, American Medical Association, the public, and the nursing profession. The Joint Commission engages in issues and activities concerning the advancement of healthcare safety and quality, including public policy initiatives, standards development, and accreditation and certification programs.⁷ The Joint Commission is the principal accrediting body for the operation of hospitals and other healthcare organizations.

The Joint Commission sets continually evolving standards for acute care hospitals and other healthcare organizations. By definition, standards establish performance expectations for entities. Standards describe what needs to be done and provide enough detail for professionals to make decisions on how best to accomplish any given standard in their individual organizations. They are not instruction manuals or cookbooks and do not typically provide step-by-step instructions on how every step in the process gets accomplished and by whom. Rather, they outline common expectations by suggesting a framework.

The Joint Commission standards that are relevant to pharmacy include those for medication management, infection control, patient care, medical records, safety and security, education, performance improvement, and environment of care (i.e., facilities). In addition to the standards, The Joint Commission has developed National Patient Safety Goals (NPSGs) that address specific patient safety issues.⁸ Some of these goals are medication related. Each standard and NPSG includes one or more elements of performance (i.e., “the specific action(s), process(es), or structure(s) that must be implemented in order to achieve the goal of a standard”). Accreditation is for 3 years.

The American Osteopathic Association’s (AOA) HFAP is the principal accreditation agency for osteopathic medical colleges and healthcare facilities. HFAP accreditation is not limited to osteopathic hospitals, and some healthcare organizations are accredited by both HFAP and The Joint Commission. HFAP standards address all departments and functions, including pharmacy services and medication use.¹⁰ Some HFAP standards are more prescriptive than other accreditation standards and CMS standards. Therefore, compliance with other accreditation standards or CMS standards is not necessarily sufficient to meet HFAP standards and vice versa. If HFAP finds an organization compliant with its standards, it lists the organization as accredited. Accreditation is for 3 years.

DNV-GL Healthcare’s NIAHO® is another option for accreditation. The NIAHO standards integrate requirements based on the CMS Conditions of Participation with International Organization for Standardization (ISO) 9001 Quality Management System requirements.¹¹ The ISO 9001 standards are global principles designed to provide assurance that quality is embedded in supplier-customer relationships (i.e., healthcare systems-patients). NIAHO is designed to facilitate the development and implementation of a Quality Management System for

KEY POINT . . .

To be accredited by The Joint Commission, HFAP, CIHQ, or NIAHO, pharmacists must work cooperatively with other departments and professionals.

. . . SO WHAT?

Deficiencies within the medication-use system are the responsibility of pharmacists, no matter where they occur in an institution.

Meeting accreditation standards for medication use requires pharmacists to understand where medications go, how they are used, the individuals involved, and the outcomes achieved. This can be done only by collaborating with physicians, nurses, and other healthcare professionals.

healthcare organizations. The NIAHO standards require that a hospital become compliant with ISO 9001 within 3 years of the first NIAHO accreditation. If NIAHO finds an organization compliant with its standards, it lists the organization as accredited. Accreditation is for 3 years.

CIHQ is a consulting organization that provides accreditation and regulatory supportive services. In 2013, CMS granted CIHQ deemed status for its acute care hospital accreditation program. The CIHQ standards are based almost exclusively on the CMS Conditions of Participation and Interpretive Guidelines for Acute Care Hospitals with few additional standards. If CIHQ finds an organization compliant with its standards, it lists the organization as accredited. Accreditation is for 3 years.¹²

Healthcare organizations undergo surveys (i.e., evaluations) to determine their level of compliance with accreditation standards and goals. Surveyors review key systems, assess compliance with relevant standards, and determine how well the organization provides care, treatment, and services. If the accrediting agency finds an organization compliant with the standards (and, if surveyed by The Joint Commission, the NPSGs), it lists the organization as accredited. Accreditation is typically awarded for 3 years. Note that The Joint Commission, HFAP, NIAHO, and CIHQ accredit healthcare organizations—not departments and services. Pharmacists must work with other departments and professionals in their organization to ensure that their organization complies with the standards.

Preparing for an Accreditation Survey Visit

ASHP's *Assuring Continuous Compliance with Joint Commission Standards: A Pharmacy Guide* provides complete guidelines for compliance with standards relating to pharmacy and guidance in preparing for survey visits from The Joint Commission, as well as CMS, HFAP, and NIAHO.¹³ The Joint Commission's *Accreditation Survey Activity Guide for Healthcare Organizations* helps hospitals understand the Joint Commission's accreditation process, what to expect during a survey, and other information needed to assure a smooth survey experience.¹⁴ The Joint Commission publishes its standards in the *Comprehensive Accreditation Manual for Hospitals: The Official Handbook (CAMH)*. The CAMH includes accreditation policies and procedures, accreditation participation requirements, the latest standards, compliance information, how to gauge compliance, and a glossary of terms.¹⁵ The Joint Commission also publishes standards for ambulatory care, behavioral healthcare, home care, long-term care, and other healthcare organizations. AOA publishes the HFAP standards in *Accreditation Requirements for Healthcare Facilities*.¹⁶ DNV-GL Healthcare publishes the NIAHO® standards in *National Integrated Accreditation for Healthcare Organizations (NIAHO®) Accreditation Requirements: Interpretive Guidelines and Surveyor Guidance*.¹⁷ CIHQ publishes its standards in the *CIHQ Accreditation Standards for Acute Care Hospitals*.¹⁸

FEDERAL AND STATE LAWS AND REGULATIONS

Laws, regulations, and rules are legal requirements that govern action. **Laws** are often imposed by an authority (e.g., federal or state government), **regulations** are governmental orders having the force of law, and **rules** address specific limited situations. The legal requirements of federal and state entities may directly or indirectly affect the practice of pharmacy. Detailed discussions of these authorities are beyond the scope of this chapter. Short descriptions of key authorities are provided below only to illustrate the complicated sets of laws and regulations governing health-system pharmacy practice.

Food and Drug Administration

The federal Food and Drug Administration (FDA)

...is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health.¹⁹

The FDA implements and enforces the federal Food, Drug, and Cosmetic Act; sets labeling requirements for food, prescription, and over-the-counter drugs and cosmetics; sets standards for investigational drug studies and product approval; and regulates and oversees the manufacturing and marketing of drugs.²⁰ Another law implemented and enforced by the FDA of importance to health-system pharmacies is the Drug Quality and Security Act (DQSA). The DQSA is composed of two separate acts:

- The Compounding Quality Act defines outsourcing compounders and creates a voluntary registration program. Compounders registered with the FDA must undergo inspections, meet specific quality standards, and submit reports of adverse events.²¹
- The Drug Supply Chain Security Act (DSCSA) enables the development of a national integrated electronic system to trace pharmaceutical products through the distribution system. The purpose of the law is to protect consumers from drugs that are contaminated, counterfeit, or stolen by verifying the legitimacy of drug products; increasing detection and notification of illegitimate products; and facilitating drug product recalls. This “track-and-trace” system will be implemented over a period of 10 years. Manufacturers, wholesale distributors, repackagers, and dispensers (mainly pharmacies) are required to participate.²²

Drug Enforcement Administration

The Drug Enforcement Administration (DEA) enforces the federal controlled substances laws and regulations. The DEA investigates and prepares for the prosecution of those who violate controlled substances laws and regulations and enforces provisions of the Controlled Substances Act relating to the manufacture, distribution, and dispensing of legally produced controlled substances.²³ Most states have a similar agency that enforces controlled substances laws at the state level. Security and accountability for controlled substances are significant challenges for healthcare organizations.

Occupational Safety and Health Administration

The mission of the Occupational Safety and Health Administration (OSHA) is to “assure safe and healthful working conditions for working men and women by offsetting and enforcing standards and by providing training, outreach, education, and assistance.”²⁴ OSHA conducts periodic workplace inspections to ensure that workers are kept safe in their jobs. OSHA standards affecting health-system pharmacies include those dealing with workplace accidents and exposure to hazardous materials. ASHP’s *Competence Assessment Tools for Health-System Pharmacies* contains materials for assessing pharmacy staff competence in handling hazardous materials.²⁵

National Institute for Occupational Safety and Health

“The National Institute for Occupational Safety and Health (NIOSH) is the federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness.”²⁶ This differs from OSHA, which sets and enforces safety standards for workers. NIOSH originated from the same legislation as OSHA (i.e., Occupational Safety and Health Act of 1970), and the differences between the two agencies can be somewhat obscure. Some NIOSH recommendations are of concern to health-system pharmacies. For example, a NIOSH Alert *Preventing Occupational Exposure to Antineoplastic and other Hazardous Drugs in Healthcare Settings* warns of the health risks to workers exposed to these drugs and recommends protection procedures for minimizing the potential adverse health effects.²⁷ In addition, NIOSH maintains a list of hazardous drugs used in healthcare, including the criteria used to identify hazardous drugs.²⁸ The NIOSH list and criteria are used by health-system pharmacies to identify hazardous drugs used in their organization to comply with OSHA’s Hazard Communication Standard. Pharmacies should ensure that their policies and procedures for handling these drugs reflect the NIOSH recommendations.

Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention (CDC) is the “United States’ health protection agency dedicated to saving lives and protecting people from health, safety, and security threats both in the U.S. and abroad.”²⁹ CDC guidelines address hand-hygiene, standard (or universal) precautions, safe injection practices, and other infection control issues that must be considered when developing organization and department practices.

Patient Protection and Affordable Care Act

On March 23, 2010, then President Barack Obama signed the Patient Protection and Affordable Care Act (ACA, also known as Obamacare) into law.³⁰ The goal of the new regulation was to require most U.S. citizens and legal residents to have health insurance. More importantly, the government wanted to lower the cost of healthcare and raise the quality. This would ensure the skyrocketing cost of Medicare and Medicaid would be capped and eventually reduced. From its inception, the ACA has been a politically charged regulation that has seen much controversy and disagreement between political parties.

The ACA allows more people access to Medicare and Medicaid programs than ever before. The federal government feels if everyone has health insurance, they will be more inclined to visit their physician when they become sick instead of waiting until their illness turns into an expensive emergency. Over time, this will decrease the overall cost of healthcare. Hospitals are forced to become more efficient and to reduce their own costs to maintain their profitability and handle this new influx of patients.

The ACA is complicated and purposefully designed to be adjusted periodically. It is made up of multiple programs, each of which is complex in its own right. Most of the programs require hospitals to meet predetermined performance measures or indicators that are evidence based. If hospitals fall below their risk-adjusted threshold for the measures, they may incur penalties that will affect their Medicare reimbursement. Many of the measures and penalties are adjusted annually to foster continuous improvement. To promote transparency, institution-specific results for performance measures are posted on CMS’s public website, Hospital Compare.³¹

To administer the ACA, CMS implemented several new initiatives directed at hospitals and healthcare providers. As they progressed, CMS began to transform itself from a passive payer of services into an active purchaser of higher quality, affordable care. During this time, the CMS Quality Improvement Roadmap was unveiled, citing several of Medicare’s goals:

- Payment incentives for quality care
- Penalties for poor or substandard care
- Joint accountability among care providers
- Increased effectiveness
- Assurance of patient access to care
- Increased safety and transparency
- Provision for smooth transitions of care
- Electronic health records (EHR)³²

CMS's initiatives can be divided into three groups or **domains**:

1. Delivery System Transformation
2. Patient Safety
3. Cost and Quality

Delivery System Transformation

The Delivery System Transformation domain aims to transform the way in which health-care is delivered to the patient. For hospitals and the system (in general) to become more efficient, major changes must take place. One of the key elements for optimizing healthcare delivery systems is to improve the patient's health record. Previously, health records were hard copy and difficult to share between healthcare institutions and healthcare providers. Therefore, CMS's Roadmap called for the development of an **electronic health record (EHR)**.³³ The Medicare Electronic Health Record Incentive Program provides incentive payments for eligible acute care inpatient hospitals that are *meaningful users* of certified EHR technology. Because of this, the program is referred to as the Meaningful Use program. Hospitals are incentivized to participate in the program by receiving "extra" dollars that they would not be eligible for otherwise. Due to the difficulty and magnitude of implementing Meaningful Use, it was divided into three stages and spread out over several years. Individual, precise components of the EHR are targeted to be addressed at specific intervals of the timeline. Medication-related components that directly affect the pharmacy include the patient's medication list, medication allergies, drug-drug and drug-allergy interaction checks, and others.

The pressure to change delivery systems has spawned new organizational structures. Some of the most well-known and ambitious delivery systems are the accountable care organizations (ACOs).³⁴ There is no standard definition of an ACO. They are all different; however, they share many of the same elements. In general, ACOs are partnerships of healthcare providers that may include primary care physicians, specialists, and even hospitals. They all agree to a defined budget that provides all the healthcare and long-term care needs for a specific population. ACOs are incentivized to keep patients healthy, treat them effectively and efficiently when they become sick, and control the effects of chronic illnesses of its patients. They promote patient wellness and the coordination of healthcare providers to change their members' lifestyle to promote better health. To control overall costs of the plan, ACOs share profits if costs are under budget and may share losses if costs are over budget.

Patient Safety

The Patient Safety domain focuses on the safety of patient populations. Many of the standards and regulations that govern how a hospital operates are based on patient safety. There has been a long-standing focus on processes that foster a safer healthcare environment. Medicare's Conditions of Participation require hospitals to implement safe processes to enable them to participate in governmental reimbursement programs. In 2008, Medicare identified certain **hospital-acquired conditions (HACs)** for which hospitals would not be reimbursed if they existed.³⁵ HACs are adverse medical conditions acquired by a patient

during a hospital stay that were not present on admission to the hospital. Some HACs are directly or indirectly tied to the use of medications. HACs, sometimes referred to as “Never Events,” are characterized by at least two of the following conditions:

- Are high cost or high volume or both
- Result in a higher payment when present as a secondary diagnosis
- Could reasonably have been prevented using evidence-based guidelines

The Hospital-Acquired Condition Reduction Program was established as part of the ACA and incentivizes hospitals to reduce their HACs. It penalizes hospitals that do not meet certain risk-adjusted HAC quality measures. These hospitals can have their Medicare payments drastically reduced compared with what they would have been paid for a similar discharge previously. Furthermore, information gleaned from the HAC Reduction Program is published on CMS’s public website, which gives consumers accessibility to valuable information when choosing their healthcare providers.

One goal of the Patient Safety domain is to improve care transitions.³⁶ As patients move through a healthcare system, many transitions or handoffs are made as the patient moves from one level of care to another. Whenever patients reach these junctions of care, the chances for medical errors increase. One good example is the breakdown of communication. Good communication is essential in providing excellent healthcare. Communication among healthcare providers must be present, concise, and interpreted in only one way. Pharmacy is dependent on good lines of communication between physicians and nursing staff to ensure correct and timely delivery of patients’ medications. There are many opportunities for communication to falter during a patient’s admission to the hospital, during patient transfers, and during patient discharge. Hospitals must be diligent in developing good lines of communication, and all employees must be attentive at all times to follow them.

Another important target for the Patient Safety domain is **hospital readmissions**. Patient readmissions are very costly for hospitals, and patients are exposed to risks they would not have encountered had they remained outside of the hospital. The ACA established the Hospital Readmissions Reduction Program that aims to reduce CMS reimbursement to hospitals with excessive patient readmissions.³⁷ Goals for the readmission reduction program include:

- Evaluation of the entire spectrum of care that the hospital and their affiliates provide to patients
- Identification of system-wide changes that make patient care safer and more effective
- Development of interventions that reduce complications of care
- Improved assessment of patients’ readiness for discharge
- Improved discharge instructions
- Improved medication reconciliation
- Improved transition of patients to outpatient care or other institutional care

When first established, the program focused on three costly, high-risk diagnoses: acute myocardial infarction, heart failure, and pneumonia. Over time, other diagnoses have been added to the program, and the penalty for excessive readmissions has increased. Hospitals are measured using risk-adjusted criteria and penalties are applied to all discharges, not just the three diagnoses in focus. The thought is, if hospitals can reduce the readmission rate of patients with these three costly diagnoses, they will improve processes that would reduce readmissions in all other diagnoses too. Pharmacy can positively impact the hospital’s goal of lower readmissions by providing medication reconciliation during admission,

interacting with physicians and other healthcare providers during the patient's hospitalization, providing medication information on patient discharge, and providing medication counseling and follow-up post discharge.

Cost and Quality

For all the changes in healthcare brought about by the federal government in recent years, the driving forces have been cost and quality. Over time, CMS has transformed their reimbursement programs from a pay-for-service to a pay-for-performance model. Congress authorized the Hospital **Value-Based Purchasing (VBP)** Program as a part of the ACA.³⁸ This program combines the VBP concept and Medicare's largest spending area, the acute care inpatient population in over 3,500 hospitals across the United States. Hospitals are now reimbursed based on the *quality* of the care they provide to patients, not just the *quantity* of the services they provide. As in other programs, quality indicators have been implemented and hospitals are measured using risk-adjusted criteria. Hospitals that fall below the threshold may receive penalties that affect their overall reimbursement.

Some quality indicators measure patient satisfaction. The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey was designed as a standardized survey tool for all qualifying hospitals.³⁹ The HCAHPS survey is composed of 27 questions and measures the patient's perception of the care received during hospitalization. Seven of the questions mention medications either directly or can be positively impacted by pharmacy involvement. Patients must meet minimum criteria to be eligible, and selection to participate is randomized. The hospital or a HCAHPS vendor may administer the survey. Results are aggregated, and information is published on the Hospital Compare website; it is available to the public. If hospitals fall below their established threshold, they may incur penalties that affect their overall Medicare reimbursement.

Other quality indicators are clinical in nature. These clinical quality measures are sometimes referred to as *core measures*. Core measures were developed for inpatients, outpatients, and other areas of care. The ACA mandates the assessment of hospitals using established, evidence-based clinical measures.⁴⁰ Core measures have been identified for multiple diagnoses such as acute myocardial infarction, heart failure, pneumonia, and venous thromboembolism. For a current listing of clinical core measures, refer to the CMS website because new diagnoses are added frequently. Many core measures contain evidence-based requirements for use of specific medications for a specific diagnosis. Results are aggregated, and information is posted on the CMS website. If hospitals fall below their established baseline, they may incur penalties that can lower their overall Medicare payment.

As stated, the ACA is a complex regulation that aims to increase the quality of healthcare and decrease its cost. The regulation continues to evolve to include new criteria as new evidence-based medicine becomes a reality. Higher penalties are imposed for hospitals as CMS strives to drive compliance. Because the ACA is an act of Congress and many of its programs are directly tied to politics, it is safe to say there will be more changes coming.

Office of Inspector General

The mission of the Office of Inspector General (OIG) is to protect the integrity of certain governmental programs as well as the health and welfare of the program's beneficiaries. OIG duties are fulfilled through a nationwide network of audits, investigations, inspections, and other related functions.⁴¹

Environmental Protection Agency

The Environmental Protection Agency (EPA) is responsible for developing and enforcing regulations pertaining to environmental laws and issues. It also conducts research and provides information and education on environmental issues and works with state and local

governments as well as businesses to protect human health and the environment.⁴² The EPA enforces the Resource Conservation and Recovery Act (RCRA) that regulates the handling and disposal of hazardous waste from the point of generation to final disposal.⁴³ The RCRA applies to hazardous waste pharmaceuticals discarded by healthcare organizations.

Office for Civil Rights

The responsibilities of the Office for Civil Rights (OCR) include enforcing Title VI of the Civil Rights Act of 1964 and its amendments and certain provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996.⁴⁴ The Civil Rights Act of 1964 deals primarily with human relations management—prohibiting discrimination in employment hiring, promotion, compensation, and treatment of protected employee groups. Protected groups are those that might be discriminated against based on their gender, race, age, religion, sexual preference, height, weight, arrest record, national origin, financial status, military record, or disability.

HIPAA aims to ensure health insurance portability, reduce healthcare fraud and abuse, enforce standards for health information, and guarantee security and privacy of health information. Compliance with the act's security and privacy provisions may be particularly challenging for pharmacies.

State Boards of Pharmacy

States regulate pharmacy practice through their state boards of pharmacy (although the actual name of the agency may vary). Boards of pharmacy responsibilities include setting licensure requirements for individuals, pharmacies, and some healthcare organizations. Boards of pharmacy also establish and enforce the rules and regulations of the state's pharmacy practice act and discipline pharmacists and pharmacies. Some boards of pharmacy enforce their state's Controlled Substances Act. Specific responsibilities differ from state to state. State requirements may be more or less stringent than accreditation and certification requirements. In all cases, the most stringent requirements take precedence. Pharmacists should contact their state board of pharmacy for specific information relating to licensure and pharmacy practice in their state.

KEY POINT . . .

Boards of pharmacy establish and enforce the rules and regulations of state pharmacy practice acts and set licensure requirements for pharmacists and pharmacies.

. . . SO WHAT?

Some state boards of pharmacy seem to focus on issues of interest to community pharmacy rather than hospital pharmacy practice. Indeed, many of the rules and regulations set by state boards of pharmacy are seen as obstacles to innovative institutional pharmacy practice. For instance, some boards have established rigid technician-to-pharmacist ratios (e.g., two technicians for every pharmacist). This hinders the ability of institutional pharmacies to delegate distributional duties to highly trained technicians and free pharmacists for clinical activities.

Other Agencies

Some government agencies share responsibilities associated with certain legal requirements. For example, the Department of Health and Human Services, Department of Justice, Department of Labor, Department of Transportation, Equal Opportunity Employment Commission, Federal Communications Commission, and other government agencies share responsibilities associated with the Americans with Disabilities Act (ADA). The ADA

protects the rights of Americans with physical and mental disabilities.⁴⁵ Pharmacy departments must be aware of the provisions of the act and be prepared to make reasonable accommodations for disabled individuals. Pharmacy standards of performance must not impose an undue hardship on these individuals.

NONGOVERNMENTAL STANDARDS-SETTING ENTITIES

Nongovernmental organizations often set standards that are enforced by government agencies (e.g., FDA, boards of pharmacy) and other entities (e.g., The Joint Commission). Three examples are described below.

United States Pharmacopeia

The United States Pharmacopeia (USP) is a nongovernmental, standards-setting organization that advances public health by ensuring the quality of medicines, food ingredients, and other healthcare products; promoting the safe and proper use of medications; and verifying ingredients in dietary supplements.⁴⁶ The USP provides standards for drugs, dietary supplements, and healthcare products. These standards are published in the *United States Pharmacopeia and National Formulary*. USP Chapter <795> sets standards for nonsterile compounding.⁴⁷ USP Chapter <797> sets standards for pharmaceutical compounding of sterile preparations (e.g., personnel competence, design of facilities, beyond-use dating, storage conditions, environmental monitoring, suggested standard operating procedures).⁴⁸ USP Chapter <800> sets standards for handling hazardous drugs (sterile and nonsterile) in healthcare settings, including compounding.⁴⁹ Further discussion of USP Chapter <797> requirements is provided in Chapter 15, Sterile Preparations and Admixture Programs.

National Fire Protection Association

The National Fire Protection Association (NFPA) is “devoted to eliminating death, injury, property, and economic loss due to fire, electrical, and related hazards.”⁵⁰ Health-system pharmacies are subject to fire risks because of the large number of flammable materials (e.g., alcohol) stored there. Organization and department standards must be compliant with NFPA’s Life Safety Code⁵¹ and other provisions.

Health and Medicine Division of the National Academies

The Health and Medicine Division (HMD) of the National Academies, formerly the Institute of Medicine (IOM), is a nongovernmental, not-for-profit organization that provides a vital service by working outside the framework of government to ensure scientifically informed analysis and independent guidance. Although they do not set standards, they provide standard-setting entities with unbiased, evidence-based, and authoritative information and advice. The HMD’s many notable contributions include their ground-breaking reports, *To Err Is Human: Building a Safer Health System* (1999) and *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001).⁵²

PHARMACY PROFESSIONAL ORGANIZATIONS

Pharmacy professional organizations have established standards of practice, guidelines, and codes for their specialty areas. Through their efforts, these organizations have raised the expectations for pharmacy practice. Pharmacy organizations are prepared to educate pharmacists about the standards and assist them in implementing and maintaining practices that meet the standards. When necessary, pharmacy organizations work with accrediting bodies, governmental agencies, and other groups to ensure consistency and currency.

American College of Clinical Pharmacy

“The American College of Clinical Pharmacy (ACCP) is a professional and scientific society that provides leadership, education, advocacy, and resources enabling clinical pharmacists to achieve excellence in practice and research.”⁵³ ACCP practice resources are the foundation of clinical pharmacy standards.

American Pharmacists Association

The American Pharmacists Association (APhA) is a national professional society of pharmacists. Its mission is “to empower its members to improve medication use and advance patient care by providing information, resources, education, and advocacy.”⁵⁴ APhA’s Code of Ethics for Pharmacists states the principles that “guide pharmacists in relationships with patients, health professionals, and society.”⁵⁵

American Society of Consultant Pharmacists

The American Society of Consultant Pharmacists (ASCP) is a professional association representing consultant and senior care pharmacists. ASCP’s website provides resources and links to federal standards relating to optimal provision of pharmaceutical care to geriatric patients and other individuals residing in health-system and residential settings.⁵⁶

ASHP

The American Society of Health-System Pharmacists (ASHP) is a professional organization for pharmacists practicing in health systems. ASHP has adopted professional policy positions, statements, and guidelines that foster improvement in pharmacy practice and patient care. They “represent a consensus of professional judgment, expert opinion, and documented evidence.”⁵⁷ Because ASHP’s policy positions, statements, and guidelines are often more stringent, more explicit, and less subject to misinterpretation than Joint Commission, HFAP, NIAHO, CIHQ, and CMS standards, they can help an organization meet or exceed accreditation and certification requirements.

ASHP is also the accrediting body for practice sites that conduct pharmacy residency programs and technician training programs. ASHP standards are available on the ASHP website.^{58,59} Meeting ASHP requirements for residency accreditation and technician training can help pharmacies raise the quality of their services.

ASHP develops standards to help pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. These standards have served a vital role through providing a national evidence-based framework that has helped to guide local, state, and federal regulators and national accrediting bodies in their enforcement activities as well as providing pharmacy practitioners, hospitals and health systems, and other healthcare professionals with a strong sense of direction on the best approaches to ensuring patient safety, quality, and optimal medication-use outcomes.

KEY POINT . . .

ASHP’s policy positions, statements, and guidelines are often more stringent, more explicit, and less subject to misinterpretation than Joint Commission, HFAP, NIAHO, CIHQ, and CMS standards.

. . . SO WHAT?

ASHP helps to establish and clarify expectations of performance for health-system pharmacists. In many instances, ASHP’s policy positions, statements, and guidelines provide better guidance than standards of accreditation agencies.

The 1999 IOM report, *To Err Is Human: Building a Safer Health System*, recognized ASHP as an organization that publishes extensively on safe medication practices. The IOM noted that ASHP has developed many standards and guidelines and has widely disseminated a list of top priority actions for preventing adverse drug events in hospitals.⁶⁰ By the time the IOM published its seminal report on medical errors that essentially launched the “patient safety movement,” ASHP had, in fact, been publishing and developing standards on safe medication practice for nearly 60 years.

Adaptability of standards is important because services and the types of patients served differ from one organization to another. Differences, for example, might include the types of services a large university hospital provides (e.g., transplant and other complex procedures) with 24-hour pharmacy services as compared to a small rural hospital that might have only one pharmacist on duty for a limited number of hours. However, adaptability does not imply that standards should be different or do not apply to one setting but not another. The endpoint of the standard remains the same, but the methods and intervening steps to achieving the standard may differ. For example, it is essential to have a pharmacist review all medication orders against the patient’s profile for appropriateness before the medication is administered to the patient. However, in the case of some small and rural hospitals without 24-hour services, the order might be reviewed through the use of technology that allows a pharmacist in a remote location (from another hospital or remote-order entry service) to access the patient record and review and approve the order. In this example, the standard is the same; however, the approach to achieving the standard is different.

Ideally, consistency associated with evidence-based practices is enhanced, and patient care outcomes are ultimately improved through standardization. The practice standards developed by ASHP, *ASHP Best Practices: Position & Guidance Documents of ASHP*, represent a rich source of information on virtually every area in hospital and health-system pharmacy practice. This valuable online resource is available free to anyone who seeks to design safer and more effective medication-use systems.⁶¹ Topics include the following:

- Automation and Information Technology
- Drug Distribution and Control
- Education and Training
- Ethics
- Formulary Management
- Government, Law, and Regulation
- Medication Misadventures
- Medication Therapy and Patient Care
- Pharmaceutical Industry
- Pharmacy Management
- Practice Settings
- Research

Standards development occurs in a variety of ways depending on the type of standard being developed and the processes employed by the developing organization. The following process is used by ASHP to develop guidance documents and serves as a good example of how an organization, which represents a distinct group of professionals, approaches standards development.

STEP 1: An ASHP member council or commission recommends the development of a guidance document after considering whether the topic has the following:

- Generates a need among practitioners for authoritative advice
- Achieves some stability, and there is sufficient experience to base a guideline
- Is relevant to the practice of a significant portion of ASHP's members
- Is within the purview of pharmacy practice in hospitals and health systems
- Is without other sufficient guidance
- Does not pose significant legal risks to ASHP
- Is determined by ASHP leadership that there is room for improvement in practice and that an ASHP document would foster such improvement⁶²

STEP 2: A group of experts (usually ASHP members) on a given topic volunteer to develop a preliminary draft. Drafters are selected based on demonstrated knowledge of the topic and their practice settings.

STEP 3: The draft is sent by ASHP to reviewers who have interest and expertise in the given topic. Reviewers consist of ASHP members and selected individuals, such as other healthcare professionals, who are knowledgeable in the content area, representatives of various ASHP bodies, and other professional organizations. The draft is posted on the ASHP website to allow time for public comment. A strength of ASHP's guidelines resides in this public comment process that allows anyone who is interested in commenting to do so, as well as ASHP's active outreach to other interested individuals and organizations.

STEP 4: Based on the comments, a revised draft is submitted to the appropriate ASHP policy-recommending body for action. When the draft meets the established criteria for content and quality, that body recommends the ASHP Board of Directors approve the document.

The guidance documents developed by ASHP are voluntary and do not have the force of law or regulation. However, it is sometimes the case that a state board of pharmacy or federal regulator such as the FDA or national accrediting body (e.g., The Joint Commission) might look to ASHP guidelines to provide a framework for the development of laws, regulations, and enforceable standards. When one compares ASHP guidelines to Joint Commission Medication Management standards published in the *Comprehensive Accreditation Manual for Hospitals: The Official Handbook*, it is evident how ASHP practice standards provide a framework for the development of enforceable standards by other organizations.

Standards for the practice of pharmacy in hospitals and health systems are, and continue to be, integral to the safe and effective use of medications. More important than gaining an understanding of how practice standards are developed and used, is for individual pharmacy practitioners to contribute to the practice standards development process throughout their entire careers, remembering the best standards are those developed by the professionals who are engaged in the practice and will be most affected by the standards once they are implemented.

ASHP dedicates significant resources to the development of practice standards to advance overall public health related to medication use and the practice of pharmacy in hospitals and health systems. It can be difficult to judge at the time a standard is conceptualized and developed whether that standard will ultimately have an impact on improving patient care or advancing pharmacy practice. However, evidence to date suggests most issues rising to the level of standards development are ones that, either immediately or over a period of time, have made a measurable difference in the lives of the patients we serve.

INFLUENCE BY INTERNAL BODIES

Although accrediting bodies, regulatory agencies, professional organizations, and other standards-setting entities define external requirements and expectations, healthcare organizations must develop internal requirements (i.e., standards) that are specific to their needs. Important health-system bodies influencing pharmacy practice are the pharmacy and therapeutics (P&T) committee and medical executive committee of each institution. They provide oversight and approval of standards of performance for the organization and each department. Other health-system bodies that play a role in pharmacy practice include the infection control, quality/performance improvement, and safety committees as well as the institutional review board.

ORGANIZATION AND DEPARTMENT STANDARDS

Organization and department standards must establish the management framework to ensure compliance and quality of care. External and internal requirements must be integrated into organization and department policies and procedures, competence requirements, performance evaluations, and performance improvement programs. Pharmacy assessments should include compliance with their organization and department standards.

Bylaws, Rules, Regulations, Policies, and Procedures

An institution's medical staff bylaws, rules, and regulations provide the framework for governing the organization. Policies and procedures are the formal, approved description of how a process is defined, organized, and carried out. Pharmacy departments must comply with their institution's bylaws, rules, and regulations. Departmental policies and procedures must be consistent with the organization's requirements and should be developed with the input of pharmacists and support staff. Policies and procedures should be used in orientation, education, and training of staff and competence assessment.

KEY POINT . . .

The P&T and medical executive committees are the two primary bodies influencing pharmacy practice within institutions.

. . . SO WHAT?

In most institutions, the levers of influence over pharmacy practice lie within these two bodies. The individuals within these committees must support the initiatives designed to improve medication use. Good professional relationships are needed with these individuals to advocate and lead change.

Competence Assessment and Performance Evaluation Programs

Healthcare organizations should have programs for determining that individuals are competent (i.e., have the skills, knowledge, and ability to perform a job according to defined expectations).⁶³ The Joint Commission requires its accredited organizations to define the competencies that are required and how they will be assessed, use appropriately qualified individuals to assess competence, assess competence at defined intervals, and take action when a person does not meet the competency requirements.⁶⁴

Performance evaluation programs are ongoing processes for providing feedback on job performance to staff and students as well as volunteers. Some organizations conduct performance evaluations concurrently with competence assessments. Performance expectations must be reasonable, achievable, measurable, and reflect the person's job responsibilities, adherence to policies, and predefined behavioral requirements. Pharmacy leader-

ship and staff should work together to develop expectations that are mutually agreeable. ASHP's *Competence Assessment Tools for Health-System Pharmacies* contains job descriptions, performance evaluations, study materials, tests, skills assessment checklists, and guidelines for assessing the competence of pharmacists and support staff.⁶⁵

Performance Improvement Programs

Most healthcare organizations have active **performance improvement (PI)** programs designed to improve processes related to care, treatment, and services. PI programs are evolving. Although approaches vary, most contain elements of quality control and **quality improvement**.

The Joint Commission's approach to PI includes outcome, process, and structure measures and reflects current standards of practice. The Joint Commission's PI standards require a proactive, organization-wide program that includes the following:

- Monitoring performance and collecting data
- Aggregating and analyzing data
- Analyzing undesirable patterns and trends in performance
- Identifying and managing sentinel events
- Using information from data analysis, to identify and prioritize opportunities for improvement
- Enhancing performance by taking action on improvement opportunities
- Evaluating those actions for effectiveness and taking further action when improvement is not achieved or sustained⁶⁶

CMS and other accrediting organizations (DNV-GL Healthcare, HFAP, CIHQ) have similar approaches to PI in their standards.

Many organizations coordinate their PI program with their risk management activities (i.e., determining, identifying, and preventing adverse patient and employee events).



SUMMARY

Health-system certification and accreditation requirements and pharmacy guidelines form a basis for setting pharmacy standards. Compliance with accreditation and certification standards, while voluntary, is essential for an organization. Meeting the minimum requirements of state and federal legal entities is mandatory. Certain nongovernmental organizations set standards that are enforced by governmental agencies or other entities. Standards established by pharmacy professional organizations are often optimal and may be more challenging than accreditation and legal requirements. Internal requirements (e.g., organization and department standards) must be consistent with external requirements. Whatever the source and whether voluntary or mandatory, compliance with these requirements raises the level of pharmacy services and improves the quality of patient care.

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CHAPTER REVIEW QUESTIONS

1. **Accreditation and certification are very similar in their purpose.**

- a. True
- b. False

Answer: a. True. Accreditation attempts to *determine* if an organization has met requirements of an accrediting body, while certification attempts to *confirm* that requirements have been met by a certifying institution.

2. **Failure to meet established thresholds for ACA performance measures may affect a hospital's Medicare reimbursement.**

- a. True
- b. False

Answer: a. True. If hospitals fall below their risk-adjusted threshold for ACA performance measures, they may incur penalties that will affect their Medicare reimbursement.

3. **The federal law that establishes safeguards to ensure the security and privacy of patient health information is the _____.**

- a. Patient Protection and Affordable Care Act
- b. Health Insurance Portability and Accountability Act (HIPAA)
- c. Drug Supply Chain Security Act (DSCSA)
- d. Occupational Safety and Health Act

Answer: b. The Health Insurance Portability and Accountability Act (HIPAA) establishes safeguards to ensure the security and privacy of patient health information.

4. **When state and federal laws both have requirements for pharmacy practice, pharmacists can choose the least stringent requirement—either state or federal—and follow it.**

- a. True
- b. False

Answer: b. False. In all cases, the most stringent requirements—state or federal—take precedence. Following the least stringent requirement can leave a pharmacist subject to legal action.

5. Joint Commission-accredited organizations are automatically eligible to participate in Medicare programs.

- a. True
- b. False

Answer: a. True. CMS deems Joint Commission standards to be equivalent or better than those of the Medicare program.

6. The federal law enabling the development of a national integrated electronic system to trace pharmaceutical products through the distribution system is the _____.

- a. Compounding Quality Act
- b. Resource Conservation and Recovery Act
- c. Drug Supply Chain Security Act
- d. Patient Protection and Affordable Care Act

Answer: c. The Drug Supply Chain Security Act (DSCSA) enables the development of a national integrated electronic system to trace pharmaceutical products through the distribution system.

7. Which of the following is NOT a governmental organization?

- a. CDC
- b. USP
- c. OSHA
- d. DEA

Answer: b. The United States Pharmacopeia (USP) is a nongovernmental, standards-setting organization that advances public health by ensuring the quality of medicines, food ingredients, and other healthcare products; promoting the safe and proper use of medications; and verifying ingredients in dietary supplements.

8. Results of ACA's performance measures for hospitals are available to the public.

- a. True
- b. False

Answer: a. True. Institution-specific results for ACA performance measures are posted on CMS' public website, Hospital Compare.

9. The IOM report, *To Err Is Human: Building a Safer Health System*, was the stimulus for ASHP to begin developing standards on safe medication practices in institutions.

- a. True
- b. False

Answer: b. False. ASHP has been publishing and developing standards on safe medication practice for nearly 60 years.

10. Which of the following professional organization's primary mission is to represent pharmacists serving senior citizens?

- a. ASCP
- b. ASHP
- c. APhA
- d. ACCP

Answer: a. The American Society of Consultant Pharmacists (ASCP) is a professional association representing senior care pharmacists.

CHAPTER DISCUSSION QUESTIONS

- 1. What can pharmacies do to become a strategic asset, instead of a cost center, for health-care organizations?
- 2. What is the role of pharmacists in organization-wide processes such as the HCAHPS program, readmission reduction initiatives, and the reduction of healthcare-acquired conditions?
- 3. One of the characteristics of any profession is that it be self-regulating. Do you believe that the practice of health-system pharmacy is regulated by pharmacists or by others? Explain your answer.
- 4. Where do you think pharmacists can have the greatest impact on the regulation of practice within their institutions?

CHAPTER 4

Medication Management

Kathy A. Chase



LEARNING OBJECTIVES

After completing this chapter, readers should be able to:

1. Describe the purpose of a formulary system in managing medication use in institutions.
2. Discuss the organization and role of the pharmacy and therapeutics committee.
3. Explain how formulary management works.
4. List the principles of a sound formulary system.
5. Define key terms in formulary management.



KEY TERMS AND DEFINITIONS

- **Closed formulary:** A list of medications (formulary) that limits access of a practitioner to some medications. A closed formulary may limit drugs to specific physicians, patient care areas, or disease states via formulary restrictions.
- **Drug formulary:** A continually updated list of medications and related information, representing the clinical judgment of pharmacists, physicians, and other experts in the diagnosis and/or treatment of disease and promotion of health.
- **Drug monograph:** A written, unbiased evaluation of a specific medication. This document includes the drug name, therapeutic class, pharmacology, indications for use, summary of clinical trials, pharmacokinetics/dynamics, adverse effects, drug interactions, dosage regimens, and cost.
- **Drug therapy guidelines:** A document describing the indications, dosage regimens, duration of therapy, mode(s) of administration, monitoring parameters, and special considerations for use of a specific medication or medication class.
- **Drug-use evaluation (DUE):** A process used to assess the appropriateness of drug therapy by evaluating data on drug use in a given healthcare environment against predetermined criteria and standards.
 - **Diagnosis-related DUE:** A drug-use evaluation completed on patients with a specific disease state or diagnosis. An example is the use of antibiotics in patients with community-acquired pneumonia.
 - **Drug-specific DUE:** A drug-use evaluation completed on a drug (medication).
 - **Prescriber-related DUE:** A drug-use evaluation completed on patients managed by a specific physician or physician group. For example, selected antibiotics may be limited to infectious disease specialists.
- **FOCUS-PDSA:** A performance improvement model used by hospitals and health systems. It includes the performance improvement elements of measuring the output of the process and modifying the process to improve the outcome.

- **Formulary restriction:** The act of limiting the use of specific formulary medications to specific physicians based on areas of expertise (e.g., cardiology), patient disease state (e.g., acute myocardial infarction), or location (e.g., operating room).
- **Formulary system:** An ongoing process whereby a healthcare organization, through its physicians, pharmacists, and other healthcare professionals, establishes policies on the use of drug products and therapies and identifies drug products and therapies that are the most medically appropriate and cost-effective to best serve the health interests of a given patient population.
- **Health-system board:** A committee of hospital and community members chosen to govern the affairs of a hospital or health system.
- **Medical executive committee:** A committee of the hospital medical staff that has the primary authority for activities related to self-governance and for performance improvement of the professional services provided by all practitioners privileged through medical staff process.
- **Medication-use review:** A performance-improvement method that focuses on evaluating and improving medication-use processes with the goal of optimal patient outcomes.
- **Nonformulary agent:** A medication that is not a part of the drug formulary. This may be due to the medication not being considered for formulary addition or the medication being considered but the pharmacy and therapeutics (P&T) committee choosing not to add it.
- **Open formulary:** A list of medications (formulary) that has no limitation to a practitioner's access.
- **Order entry rules:** Logic established within the hospital information system order entry module to notify prescribers of adverse effects, drug interactions, monitoring required, or other actions required.
- **Outcome assessment:** A systematic process of evaluating a medication's appropriateness, safety, and efficacy. The process involves review of patient medical records to evaluate the drug use against predetermined criteria and standards.
- **Pop-ups:** Information that appears on a computer monitor when specific actions are taken. Hospital information systems often use *rules* to determine when pop-ups will occur. These pop-ups may contain clinical information about medication use, potential drug interactions, recommended monitoring, etc.
- **Stop orders:** Physician orders that are automatically terminated. The P&T committee may establish stop orders for medications that require additional evaluation after a specific time. Examples of stop orders are antibiotic therapy stopped after 7 days and nesiritide therapy stopped after 24 hours.
- **Therapeutic class review:** An evaluation of a group of medications with an established therapeutic class (e.g., first-generation cephalosporins). The review evaluates the indications for use, pharmacokinetics/dynamics, adverse effects, drug interactions, dosage regimens, and cost to determine similarities and differences.
- **Therapeutic equivalent:** Drug products with different chemical structures but of the same pharmacologic or therapeutic class and usually having similar therapeutic effects and adverse-reaction profiles when administered to patients in therapeutically equivalent doses.
- **Therapeutic interchange:** Authorized exchange of therapeutic alternatives in accordance with previously established and approved written guidelines or protocols within a formulary system.



INTRODUCTION

Medication-use management describes the process used to ensure the safe and effective use of drugs in a cost-conscious manner. Key to medication management in the health-system environment is the formulary system. The formulary system is a mechanism for ongoing assessment of medications that are available for use. A committee of experts, which includes pharmacists and physicians, manages the system.

This chapter will discuss the medication management system with focus on the following:

- Formulary system
- Pharmacy and therapeutics committee
- Formulary management
- Drug-use evaluation
- Medication-use policies
- Published formulary

THE FORMULARY SYSTEM

A **drug formulary** is a continually updated list of medications and related information representing the clinical judgment of pharmacists, physicians, and other experts in the diagnosis and/or treatment of disease and promotion of health. It is often described as a list of medications routinely stocked by the healthcare system. The formulary, developed by hospitals in the 1950s as a management tool, was initially used to ensure that physicians had an adequate and consistent supply of medications for their day-to-day needs. A key purpose of the formulary was to discourage the use of marginally effective drugs and treatments.

Over time, the formulary has evolved beyond a simple list of medications. It is now one element of a system that includes medication-use policies, a pharmacy and therapeutics (P&T) committee, medication-use evaluation (MUE), and formulary management. The formulary today can be more accurately defined as a continually updated list of medications and related information representing the clinical judgment of pharmacists, physicians, and other experts in the diagnosis and/or treatment of disease and promotion of health.

Formularies are fundamental to the **formulary system**—an ongoing process that methodically evaluates medications on an ongoing basis for inclusion or exclusion; establishes guidelines for optimal medication use; and develops policies and procedures for prescribing, dispensing, and administering medications. The P&T committee or equivalent group made up of an organized team of medication system experts manages the formulary system.

KEY POINT ...

The formulary has evolved beyond a list of medications to a system that manages the drug-use process.

... SO WHAT?

Standard definitions of formularies refer to them as static compilations of recommended medications in a pharmacy. In truth, they are really dynamic entities consisting of a constantly changing medication list, policies and procedures for managing that list, and tools used to encourage appropriate use of medications on that list (e.g., therapeutic substitution, drug utilization review).

There are advantages and disadvantages to a formulary system. The primary advantage is that it provides a systematic method to review scientific evidence on clinical effectiveness and cost effectiveness in drug selection decision, thus potentially improving health outcomes while reducing costs. A major disadvantage, however, is that an overly restrictive formulary system may potentially reduce the quality of care by limiting access to clinically indicated medications.

THE PHARMACY AND THERAPEUTICS COMMITTEE

The P&T committee has oversight for medication management in the health system. Specific regulatory or accrediting bodies may confirm this accountability. To be effective, the committee must have the support of the individual members as well as the health system and medical staff as a whole.

Organization

The committee is generally a policy-recommending body to the medical staff through the **medical executive committee**—a group of the hospital medical staff in charge of institutional governance and performance. The committee is responsible to the medical staff as a whole, and its recommendations are subject to approval by the organized medical staff as well as the routine administrative approval process. More recently, in some organizations, the P&T committee has reported directly to a nonmedical staff advisory committee of hospital and community members called a **health-system board** rather than a local medical executive committee.

Because drug products and medical literature are continually changing, meetings should occur at least four to six times per year. Generally, monthly meetings are needed to keep the meeting time to 60–90 minutes.

Subcommittees or task forces have been established to facilitate meeting efficiency. Examples of subcommittees include medication safety, drug review panels, and **medication-use review**. The medication safety task force may be charged with review of adverse drug events and medication errors, their trending, and development of plans for prevention of future events. Drug review panels may be focused on a particular specialty, such as cardiology or infectious disease, and review drug products and guidelines in their area of specialty. Often the drug review panels are aligned with clinical service lines that the hospital or health system has established. The medication-use review task force may monitor one or more medication-use reviews, and evaluate the data and development plans to optimize specific drug use. **Figure 4-1** illustrates how these subcommittees relate to the organizational structure of the P&T committee.

It is important to establish rules for a quorum to make certain that key stakeholders are represented at meetings. Such rules may establish a minimum number of members that must be present to conduct a meeting or a minimum number of member types that must be present to conduct a meeting. For example, a committee with 15 members might be required to have at least five members present, of which two must be physicians and one must be a pharmacist before a quorum has been established.

The integration of hospitals within health systems has resulted in the establishment of system formularies managed by system P&T committees. These committees often meet every other month making decisions for all health-system hospitals. The next month a local hospital P&T committee may meet to endorse the system actions and determine if they are applicable to their patient population. For example, if the system P&T committee were to select a specific surfactant agent and the local hospital does not care for babies, they may choose not to add the agent because it is not applicable to their patient population.

Committee Membership

P&T committee membership should include pharmacists, nurses, physicians, administrators, risk or quality improvement managers, and others as appropriate. These members are selected with the guidance of the medical staff. Medication management is a multidisciplinary process. Committee membership should include nonphysician members such as nurses, respiratory therapists, and other healthcare professionals. The addition of information technology (IT) professionals is becoming more common. Their input may be beneficial as the committee reviews and approves therapeutic guidelines facilitated through the hospital electronic ordering system. Although the voting members of the P&T committee in many hospitals remain the physician members only, this is changing as the committee membership is evolving.

KEY POINT ...

Medication management is a multidisciplinary process.

... SO WHAT?

Even though it is called the *pharmacy* and therapeutics committee, representation on the committee often includes physicians, nurses, and respiratory therapists given their roles within the medication-use process. The collective effort of all of the disciplines is needed to achieve optimal health outcomes.

Responsibilities

The committee performs the following functions:

- Establishes and maintains the formulary system.
- Selects medications for formulary inclusion by considering the relative clinical, quality-of-life, safety, and pharmacoeconomic outcomes. Decisions should be balanced to all of the above. Decisions should include consideration of continuity of care (e.g., local health plan formularies).
- Evaluates medication use and related outcomes.
- Prevents and monitors adverse drug reactions and medication errors.

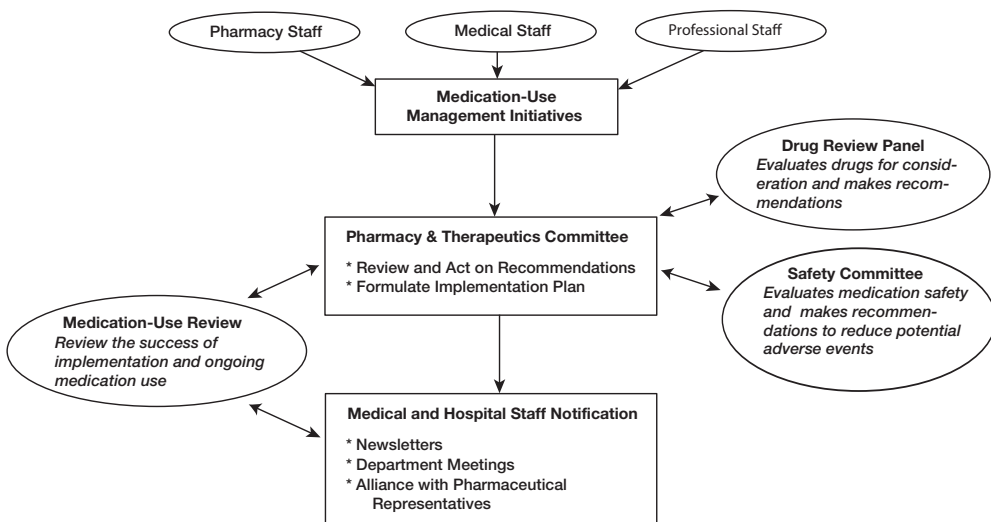


FIGURE 4-1. Formulary management process.

- Evaluates or develops and promotes use of drug therapy guidelines.
- Develops policies and procedures for handling medications to include their procurement, prescribing, distribution, and administration.
- Educates health professionals to the optimal use of medications.

Formulary System Maintenance

The committee develops a list of medications for use in the organization. They may also develop guidelines for the optimal use of the medications and/or for specific disease management. They review the medication list and guidelines on a regular basis to ensure that it is current and meets the needs of the medical staff and patients.

Medication Selection and Review

The committee should have established methods for medication selection and review. A written medication review is prepared from available literature. The review should be unbiased, as should the discussion of the review. Meeting participants (committee members and guests) should be required to discuss any conflict of interest prior to discussion of the drug or drug class. Medication selection criteria should consider questions such as:

- Is the medication under evaluation a duplication of an existing formulary agent? If so, what are its relative effectiveness, safety, and cost?
- How should it be used?
- When should it be used?
- Who should use it?
- Are there any other special concerns?
- For drugs that may be used upon patient discharge, are there patient access issues such as cost or availability in the community?
- How is the drug reimbursed? Is there a similar drug with better reimbursement when used in the outpatient setting?

Barriers to optimal formulary decisions may include physician experience with the drug under consideration, physician preference for other agents, detailing by pharmaceutical company representatives, and unpublished or anecdotal studies and reports. Selection criteria should be such to minimize the effect of the aforementioned barriers.

Medication-Use Evaluation

A medication-use evaluation (MUE) is the method for evaluating and improving medication-use processes with the goal of optimal patient outcomes. The P&T committee should establish a regular process for reviewing how medications are used in the health system (i.e., MUE). Medications may be considered for review based on their use, safety, cost, or a combination of factors. For example, antibiotics represent a high-use item; overuse of a particular antibiotic may place patients at risk for the development of resistant infections, and some antibiotics may also be costly. Establishment of specific criteria for use, review for compliance to the criteria, and routine review of the data is the foundation of the medication-use process. Key to the process is timely data to review, action plan development, and follow up.

Medication Safety Evaluation

Medication safety is evaluated through adverse drug reaction reports and medication error reports. Such reports may be local (i.e., from the health system) or global (i.e., literature, press releases). The impact of such reports should be considered relative to the health-system population, resources, and alternatives. A report of increased bleeding in patients over the age of 65 may not be critical in a pediatric hospital. However, reports of infusion rate reactions may require changes in nursing procedures in drug administration. Such

reports should be used in considering whether a drug is added to the formulary, retained on the formulary, or deleted from the formulary.

Drug Therapy Guidelines

Drug therapy guidelines are a listing of the indications, dosage regimens, duration of therapy, mode(s) of administration, monitoring parameters, and special considerations for use of a specific medication or medication class. In a hospital or health system, these guidelines are developed with the oversight of practitioners who have expertise in the use of a specific medication or management of a disease state. The guidelines are often put into practice via a computerized order set.

The development of drug therapy guidelines is often the result of a medication-use review or medication safety evaluation. A review of these data may indicate that the drug is not being used in an optimal manner with regard to patient selection, dosage, frequency, route, length of therapy, or a combination. The development and implementation of drug therapy guidelines may foster the safe, efficacious, and cost-effective use of selected drug products. Education of the professional and medical staff to these guidelines is critical to their success. Just as important is a method for routine review of the guidelines to ensure they are current.

Policy and Procedure Development

The P&T committee is responsible for medication use in the hospital. This includes the development of guidelines on historically pharmacy-related topics of medication procurement, selection, and distribution. In addition, they are responsible for the medication administration process. This may include determining what medications are administered in specific locations for the hospital (i.e., intensive care unit) or under specific conditions (i.e., by chemotherapy-certified nurse). Finally, they define the formulary management process, specifically, guidelines for the evaluation of medications by the P&T committee, frequency of such review, maintenance of the medication list, and so on.

Education

The P&T committee must communicate its actions to health-system staff and physicians. A newsletter is often employed to communicate these decisions. The newsletter may also include clinical information on drugs added to the formulary, drug therapy guidelines developed, and available medication safety information. The newsletter's format and content may limit its success. It should be visually pleasing, easy to follow, and succinct. Optimally, it should be limited to 2-4 pages in length. The audience is generally broad and includes physicians, nurses, pharmacists, and other healthcare professionals. Alternative methods to communicate and educate others to P&T committee actions are presentation at medical staff department meetings, nursing unit staff meetings, and pharmacy staff meetings and electronic messaging through email or the health-system website. The P&T committee may also assist in the development of programs to educate healthcare professionals or patients regarding medications.

Regulatory and Accrediting Bodies

Regulatory and accrediting bodies may require a P&T committee and define its membership and responsibilities. Regulatory bodies requiring such activity include the state department of health or board of pharmacy; this varies by state. Accrediting bodies requiring this activity include The Joint Commission, DNV-GL Healthcare, the American Osteopathic Association (AOA), and Commission on Accreditation of Rehabilitation Facilities (CARF). The facility type may define the accrediting body; each has a slightly different interpretation of the term *formulary*. Regulations and accreditation standards are dynamic and require the pharmacy's vigilance to ensure compliance.

Pharmacist Role

Pharmacists are essential to the formulary management process. Often pharmacists will guide the P&T committee activities to ensure optimal medication management. The pharmacist's responsibilities may include the following:

- Establishing P&T committee meeting agenda.
- Analyzing and disseminating scientific, clinical, and health economic information regarding a medication or therapeutic class for review by the P&T committee.
- Conducting drug-use evaluation and analyzing data.
- Recording and archiving P&T committee actions.
- Following up with research when necessary.
- Communicating P&T committee decisions to other healthcare professionals such as pharmacy, medical, and patient care staff.

FORMULARY MANAGEMENT

The formulary is the foundation of the formulary system. In its simplest form, the formulary is a list of medications available for use at a hospital or health system. This list includes the dosage forms, strengths, and package sizes of each of the medications on it. All medications used throughout the health system must be included in the formulary and formulary review process, including sample medications as well as anesthesia gases and radiopharmaceuticals, whether purchased by the pharmacy or not. Diligent management of this list has both patient care and financial implications. Patient care considerations include medication efficacy and safety. Financial considerations are the cost of the drug as well as the costs associated with stocking the medication such as shelf space, drug outdates, and handling.

Formularies can be categorized by their access to medications as open or closed. An **open formulary** has no limitation to access to a medication and is generally large. A **closed formulary** is a limited list of medications that may limit drugs to specific physicians, patient care areas, or disease states via formulary restrictions.

Formulary restrictions (i.e., limits on institutional drug use) do not necessarily translate to optimal medication management. For example, limitation of an antibiotic to a *restricted* status may result in shifting to a different antibiotic. Although this change is sometimes desirable, it may not always be the case. The *new agent of choice* may be more expensive or less safe than the *restricted* agent. Careful consideration of the impact of the formulary product selection and/or restriction is critical to the process. Some authors have suggested that restricting formularies has resulted in increased healthcare costs by increasing utilization of physician visits and hospitalizations.^{1,2} Although these data have been criticized, it is important to note the impact of formulary decisions in total

KEY POINT . . .

Formulary restrictions do not necessarily translate to optimal medication management.

. . . SO WHAT?

Formulary restrictions often have unintended consequences. For example, strict limitations on the number of antibiotics used within a hospital may allow microbes a better chance of adapting to these few medications and developing antibiotic resistance in comparison to an institution with no restrictions on antibiotic use. The key is to carefully consider the potential impact of formulary restrictions prior to implementation and to monitor the actual impact after implementation.

healthcare costs.³ The Institute of Medicine (IOM) evaluated the Veterans Administration (VA) *National Formulary* impact on healthcare costs in six closed or *preferred* classes of drugs.⁴ The IOM concluded that the VA National Formulary was cost saving, probably generating savings of \$100 million over 2 years and did not appear to have any effect on hospital admissions for selected heart- or ulcer-related conditions.

Drug product selection should be based on individual chemical entities. The Food and Drug Administration (FDA) defines the equivalence of individual chemical entities or generic equivalents. A list of such equivalents can be found in the Approved Drug Products with Therapeutic Equivalence Evaluation commonly known as the *Orange Book*.⁵ Policies for the use and dispensing of generically equivalent products should be set forth in the formulary system policy.⁵

Many health systems have also established therapeutic equivalents and therapeutic interchange programs. **Therapeutic equivalents** are drug products with different chemical structure but are of the same pharmacologic and/or therapeutic class and are expected to have similar therapeutic effects and adverse effects. Examples of therapeutic equivalents include quinolone antibiotics and proton pump inhibitors. **Therapeutic interchange** is the authorized exchange of therapeutic alternatives in accordance with previously established and approved written guidelines. Establishment of therapeutic equivalents extends beyond the chemical entity to include the dosage strength, dose frequency, and route of administration for the interchange. Examples of therapeutic interchanges are listed in **Table 4-1**.

The P&T committee should establish guidelines for generic substitution and therapeutic interchange. Such guidelines should include the following:

- The pharmacist is responsible for selecting generically equivalent products in concert with FDA regulations.
- Prescribers may specify a particular brand if clinically justified. The decision should be based on pharmacologic and/or therapeutic considerations relative to the patient.
- The P&T committee determines therapeutic equivalents and how they are processed.

The pharmacist is responsible for the quality, quantity, and source of all medications as well as chemical, biologicals, and pharmaceutical preparations used in the diagnosis and treatment of patients. Such products should meet the standards of the United States Pharmacopeia (USP) and the FDA.

TABLE 4-1

Therapeutic Interchange Equivalence by Therapeutic Class

Therapeutic Class	Generic Name	Dosage	Dosage Frequency	Route
Quinolone antibiotic	Levofloxacin	500–750 mg	Daily	IV or PO
	Moxifloxacin	400 mg	Daily	IV or PO
Proton pump inhibitors	Esomeprazole	20–40 mg	Daily	PO
	Lansoprazole	30 mg	Daily	PO
	Omeprazole	20 mg	Daily	PO
	Pantoprazole	40 mg	Daily	PO

IV: intravenous; mg: milligram; PO: oral

Formulary maintenance is the ongoing process of ensuring relative safety and efficacy of agents available for use in the health system. Processes used in formulary maintenance include the following:

- New product evaluation
- Therapeutic class review
- Formulary changes (rationale for retaining or deleting an agent from the formulary)
- Nonformulary drug-use review

New Product Evaluation

Pharmacists have the opportunity to assume a leadership role in the selection of agents to the formulary. The evaluation of an agent should consider the indications for use, pharmacokinetics, safety, and cost. Considerations to drug storage, mode of administration, special considerations, and drug-dispensing issues should also be included in the evaluation. Development of a standard format for new drug evaluations is useful in facilitating P&T committee discussions. Standard elements include the following:

- **Generic name** — List officially approved name of all chemical entities in the drug product.
- **Trade name** — List common trade name(s) of the drug product.
- **Therapeutic or pharmacologic class** — State the pharmaceutical or therapeutic class to which the agent belongs. Similar agents within the class may be listed.
- **Pharmacology** — Describe the mechanism of action and related pharmacologic effects of the drug. If the mechanism is unknown, state this.
- **Pharmacokinetics** — Describe how the drug is handled by the body. Include onset of effect, serum half-life, metabolic considerations, and route of excretion as appropriate.
- **Indications for use** — State the FDA-approved indications for use. Include any additional uses under investigation.
- **Clinical studies** — Briefly describe clinical study data supporting the indications for use. This review should be an unbiased, comparative review of studies, which identifies strengths and weaknesses as appropriate. Study description should include information about the patient populations, inclusion and exclusion criteria, study design and protocol, statistical analysis, outcomes, and conclusions.
- **Adverse effects/warnings** — List adverse effects associated with the drug and the frequency of occurrence. Describe methods to reduce or treat adverse effects. Discuss the risks and benefits of this drug therapy. Also, list any special precautions such as drug use in pregnancy and excretion of the drug into breast milk.
- **Drug interactions** — List drug-drug and drug-food interactions associated with this agent, significance of these interactions, and methods for prevention.
- **Dosage range** — List a dosage range for different routes of administration and indications for the drug. Include special dosing considerations for renal disease, age, and hepatic function.
- **Dosage form and cost** — List the dosage form and strengths proposed for formulary addition. Include the cost of each dosage form and strength. A table listing comparable agents may be useful in determining the value of a formulary addition or modification.

- **Summary** — Summarize the information provided in a single paragraph.
- **Recommendation** — State the recommendation and rationale for the recommendation. Recommended actions may include formulary addition, restriction, and deletion, or do not add to formulary.
- **References** — List references used. Reference materials useful in preparation of the formulary monograph should be unbiased and current. Peer-reviewed primary literature is optimal whenever possible. Other resources include textbooks such as *American Hospital Formulary Service Drug Information* and *Drug Facts and Comparisons*. Electronic databases such as Micromedex (www.micromedex.com), PubMed (<http://www.ncbi.nlm.nih.gov/pubmed>), and National Guideline Clearinghouse (www.guideline.gov) are often useful.

In preparing the **drug monograph**, it is important to understand the P&T committee's needs. Some committees desire a detailed analysis of the points listed above, whereas others prefer an abbreviated monograph. Critical elements to both are efficacy, safety, and cost. To assist the P&T committee membership, including tables and comparative data within a therapeutic class or indication is useful. Knowing the cost of an agent is meaningless if the cost of comparator agents is unknown. The pharmacist's recommendation should be concise; include the rationale for the decision; list any possible formulary deletions that might result by adding this agent; list guidelines for use when appropriate; and include consideration for future review. Some health systems add new agents to the formulary for a limited or *trial* period such as 3 or 6 months. This conditional approval allows the P&T committee to further assess the use and safety of the product before *final* formulary addition.

Therapeutic Class Review

The P&T committee's regular review of drug classes is useful in ensuring that optimal drug therapeutic options are available. Therapeutic class reviews should not be so broad or all-inclusive that they are not meaningful. The review of antimicrobials may be too broad, whereas the review of quinolone antibiotics may prove to be more useful. The committee may establish criteria for these reviews such as new medical information, adverse event profiles, purchase or use data, and cost. Some P&T committees conduct a therapeutic class review with each consideration for formulary addition. The objective is to have the optimal agents within a therapeutic class in terms of efficacy, safety, and cost. The end result of a therapeutic class review may be formulary modifications (i.e., additions or deletions), implementation of a drug-use review, or the development of therapeutic guidelines.

KEY POINT . . .

Conditional approval allows the P&T committee to further assess the use and safety of the product before *final* formulary addition.

. . . SO WHAT?

A "wait and see" attitude often serves a P&T committee well when deciding to add a new drug. Many new drugs on the market can have insufficient evidence of safety because they need to be tested only on a limited number of patients prior to FDA approval. In addition, utilization patterns for the new drugs by physicians will also be unclear.

Unexpected widespread adoption of a very expensive medication can bust the pharmacy drug budget. Conditional approval can help things from getting out of hand.

Formulary Changes

A process to continually update the formulary must be established and should include a method for making additions and deletions to the formulary. This process typically involves the submission of a request for formulary addition or deletion from the pharmacy or medical staff. This request may be written or verbal. Requests generally require specific information:

- Agent to be considered for addition or deletion.
- Rationale for request, which should include the impact on the cost and quality of patient care.
- Alternative agents currently on the formulary.

Some organizations require or permit the requesting individual to attend the P&T committee to support their request.

Nonformulary Drug Review

The objective of a formulary is to have the most efficacious, safe, and cost-effective agents available for routine use in the health system. On occasion, unique patient needs may require the use of a **nonformulary agent**. To prevent the erosion of the formulary system by overuse of nonformulary agents, a process for the management of nonformulary agents should be in place that includes (1) a policy for the use of nonformulary drugs, (2) procedure for procurement of nonformulary drugs, and (3) the P&T committee's regular review of nonformulary drug use. The policy for use of nonformulary drugs should include pharmacist contact with the prescribing physician to offer alternatives. It may also include the completion of the prescribing physician's nonformulary request form or the P&T committee chair's authorization prior to dispensing. The procedure for drug procurement should be well-defined and communicated to the pharmacy, medical, and nursing staff so that expectations are appropriately understood. Such a procedure may indicate up to a 24-hour delivery time for nonformulary medications. It may also permit the use of a patient's own medications in concert with other hospital policies. The P&T committee's ongoing assessment of nonformulary drug use is an important part in managing the medication process. Critical information for the committee to consider includes the agent used, formulary alternatives, number of times used in previous 6–12 months, patient safety, and cost impact. Understanding this information will allow the committee to determine an action plan that may include reconsideration of an agent for formulary addition, development of guidelines for use of a drug within a therapeutic class or disease state, or individual physician intervention.

A national survey of hospital pharmacy practice was conducted in 2007.⁶ The authors described the various formulary techniques used in their hospitals (those aforementioned in this chapter). They noted the decline of all but two of these techniques: therapeutic interchange and nonformulary medication management. The use of clinical practice or drug therapy guidelines has become a key tool in managing drug use in the health system.

A successful method of formulary management has resulted from automating the medication prescribing process. Computerized prescriber order entry facilitates the implementation and compliance with drug therapy guidelines. Formulary management oversight includes the establishment and/or review of **order entry rules** that may include weight-based dosing, required laboratory tests, and allergy checks. In addition, the P&T committee may determine the responses (**pop-ups**) to the rules through the formulary management process. Review of this information will be a key element in managing and monitoring medication use throughout the health system.

DRUG-USE EVALUATION

Drug-use evaluation (DUE) is a systematic process used to assess the appropriateness of drug therapy by engaging in the evaluation of data on drug use in a given healthcare environment against predetermined criteria and standards. MUE encompasses the goals and objectives of DUE in its broadest application, with an emphasis on improving patient outcomes. Use of *MUE* rather than *DUE* emphasizes the need for a more multifaceted approach to improving medication use.

MUE or DUE programs were first established in the 1980s. They provide an ongoing, structured, organized approach to ensure that drugs are used appropriately. More recently, the term **outcome assessment** has been used to describe such programs. The desired endpoint is the same—safe, efficacious drug therapy.

MUE programs should be incorporated into the overall hospital performance improvement process. They should employ the performance improvement model used by the health system. There are multiple performance improvement models. A common model used in health systems is **FOCUS-PDCA** or **PDSA**. The acronym is described below:

Find process to improve
Organize a team that knows the process
Clarify current knowledge of the process
Understand causes of process variation
Select process improvement
Plan
Do
Check (or **S**tudy)
Act

KEY POINT . . .

MUE encompasses the goals and objectives of DUE in its broadest application, with an emphasis on improving patient outcomes.

. . . SO WHAT?

In some respects, the differences between MUE, DUE, and outcomes assessment are arbitrary. Nevertheless, these definitions have evolved in response to a tendency for some pharmacists to see medication use only as it relates to the world of pharmacy. Therefore, compliance with formulary restrictions, pharmacy policies and procedures, and other processes are sometimes emphasized over the actual patient outcomes. Redefining terminology can refocus efforts of MUE toward achieving the goal of positive patient outcomes.

Figure 4-2 illustrates a DUE using the PDCA model for antibiotic prophylaxis for surgery.

Pharmacists can take a leadership role in designing the DUE programs. The program should measure and compare the outcomes of patients who received drug therapy in concert with approved criteria versus those who did not. Selection of agents for DUE programs should be based on whether a drug is high-use, high-cost, or high-risk. Many drugs fall into more than one category: thrombolytic agents are high-cost and high-risk; select antibiotics may be high-use. Medication-use criteria may be diagnosis-related, prescriber-related, or drug-specific.

Diagnosis-related DUE criteria identify indications for which select drug(s) may be appropriate for a given disease state. One example is the use of selected antibiotics for community-acquired pneumonia. Use of other antibiotics would fall outside the approved list and require follow up.

Prescriber-related DUE criteria identify specific physicians whom the P&T committee has determined may use certain drugs. For example, selected antibiotics may be limited to infectious disease specialists.

Drug-specific DUE criteria focus on specific aspects of a select drug such as the dose or dosing frequency. For example, the dosage regimen of a low molecular weight heparin might be reviewed. Dosage regimens outside the criteria would require action.

Pharmacists, working with key physicians, develop DUE criteria that should be focused and limited. Select three to five criteria to evaluate that are meaningful and simple to collect. If possible, data should be collected during the patient visit (concurrent) rather than retrospectively (chart review). Concurrent review often is more complete. It allows the pharmacist to obtain information from the prescriber that may not have been clear in the medical record. It also provides timely information to act on. Because medical information is dynamic, the most meaningful DUEs should reflect current practice patterns rather than those from the previous 6–18 months. The criteria should also include a number of patients to be reviewed and the time period. For example, “20 patients each month” receiving the drug are reviewed. The DUE criteria are presented to the P&T committee for their review and endorsement prior to commencing data collection.

Technology may be used to collect or screen data. Use of information systems to identify patients for review and collate the data will facilitate the process. After the data have been collected, they should be compiled for review. The use of trend graphs or control charts are helpful in identifying opportunities for improvement. The result of a DUE may be validation that drug use is appropriate and safe. However, it may also indicate an opportunity for improving the way a drug is used. Once the data are collated, it may be beneficial to form a task force to develop an action plan. This task force should include key physicians, nurses, pharmacists, and other healthcare professionals appropriate to the drug therapy under review. The task force should develop an action plan and criteria for ongoing monitoring. The action plan may include development of drug-use guidelines, preprinted orders, medication order entry *rules*, professional staff education, formulary changes, or a combination of these actions. The DUE results and action plan are presented to the P&T committee for consideration. The committee will review, endorse, and/or modify the plan for implementation and follow-up. A single drug-use evaluation should not continue indefinitely. After the desired endpoint has been achieved, an ongoing review may be discontinued or conducted less frequently (e.g., once or twice a year).

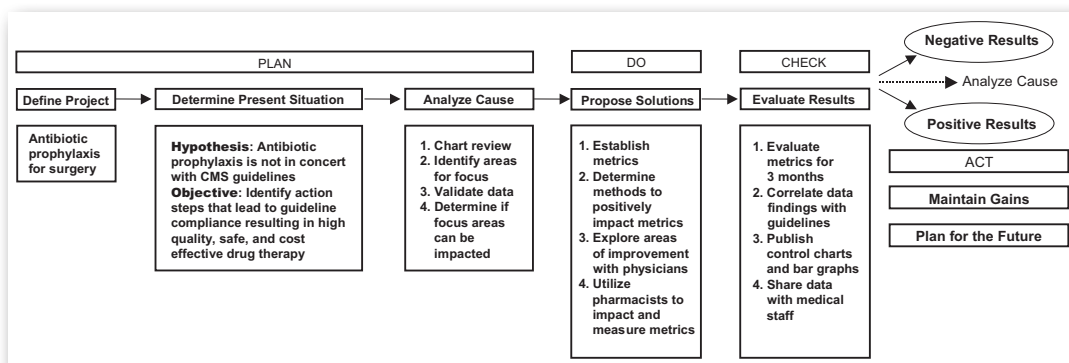


FIGURE 4-2. PDCA Model: Antibiotic prophylaxis for surgery patients.

MEDICATION-USE POLICIES

Medication-use policies are critical in medication management in healthcare settings. Such policies should include the following:

- Formulary management
- P&T committee
- Medication prescribing, dispensing, and administration

Formulary Management

Formulary policies should include information on who may use a specific agent (formulary restrictions), how a drug is added or deleted from the formulary, how a drug is stocked, and which drugs are stocked. The formulary restriction policy should specifically define how items are selected for formulary restriction, rationale for selecting approved prescribers, and a method for managing the process. A formulary policy should describe the method for drug addition and deletion as well as nonformulary drug use. A policy should describe how an agent is added to the pharmacy stock once it is added to the formulary and who gets to decide. For example, the P&T committee approves the addition of a chemical entity added and the pharmacy manager selects dosage forms, strengths, etc. Otherwise the P&T committee determines the chemical entity and dosage form(s), and the pharmacy manager selects the strengths or sizes to be stocked. The basic policies and procedures governing the formulary system should be incorporated in the medical staff bylaws or in the medical staff rules and regulations.

P&T Committee

The policy should address the committee membership, operation, and responsibilities.

Medication Prescribing, Dispensing, and Administration

Organizational policies on the prescribing, dispensing, and administration of pharmaceuticals are required and necessary to ensure safe medication use. The policies should address all aspects of the medication process:

- **Writing medication orders or prescriptions** — Defines practitioners who may write medication orders or prescriptions in concert with state and federal regulations. This or related policies may also include the format for order writing and unacceptable abbreviations.
- **Verbal orders** — Defines who may accept a verbal order and the transcription process of such an order. This policy should address the reading back of the order to confirm its accuracy.
- **Stop orders** — Defines the orders that are automatically terminated; how the prescriber is notified, if appropriate; and the method for their reinstatement. Stop orders are often established for medications that require additional evaluation after a specific time. Examples of stop orders are antibiotic therapy stopped after 7 days and nesiritide therapy stopped after 24 hours.
- **Investigational drug orders** — Defines how investigational drugs are managed in the healthcare system. This policy should include the review process as well as the method for prescribing, dispensing, administering, and monitoring investigational agents.
- **Controlled substances** — Defines the flow of controlled substances through the healthcare system. This policy should include approved prescribers, the ordering process from the pharmacy and vendor, the distribution and tracking of use, discrepancy tracking and follow-up, and management of diversion.

- **Generic and therapeutic substitution** — Defines how a drug is selected for generic substitution and therapeutic equivalents approved by the P&T committee. It should describe how an alternative agent may be prescribed if deemed medically necessary.
- **Self-administration of medications** — Defines the conditions and process for the administration of medication by the patient in the hospital setting.
- **Medication samples** — Defines the conditions and process for the use of medication samples in the hospital or clinic setting.
- **Floor stock** — Defines the criteria for selecting agents for floor stock, process for modifying the stock, and the P&T committee's regular review of the stock.
- **Definition of order interpretation** — Defines the meaning of specific types of orders including sliding scale, range, as needed, tapering, and titrating orders.
- **Medication administration times** — Defines specific medication administration times and rules for interpretation, which may include the definition of *stat* and related terminology.
- **Adverse drug reactions** — Defines an adverse drug reaction, the reporting process, and monitoring methods.
- **Medication errors** — Defines a medication error, the reporting process, and monitoring methods.
- **Others** — Other topics for policy consideration include pharmaceutical representatives, pharmacy hours of service, emergency medications, and medication delivery devices.

KEY POINT . . .

Organizational policies on the prescribing, dispensing, and administration of pharmaceuticals are required and necessary to ensure safe medication use.

. . . SO WHAT?

Policies are developed for common, well-understood problems seen in the medication-use process. They are designed to ensure that the pharmacy-provided products and services are of consistent high quality. Rather than reinventing the wheel each time a problem occurs, clear directions are given delineating responsibilities and actions. Policies are not meant to replace professional judgment of pharmacists (e.g., I know it is a bad idea; I am just following our policy). They are meant to supplement and guide pharmacists' decision making.

PUBLISHED FORMULARY

The published formulary should provide information on the medications approved for use, basic therapeutic information about each item, information on medication-use policies and procedures, and special information about medications (e.g., dosing guidelines).

Medication List

The key element of the published formulary is the list of medications approved for use, which includes both entries for each medication and indexes to facilitate use. Medication entries may be arranged alphabetically by generic and trade (synonym) names, therapeutic class, or a combination. At a minimum, each drug entry should include the following:

- **Generic name of primary active ingredient** — Combination products may be listed by generic ingredients or trade name.
- **Trade or synonym name that is commonly used** — A disclaimer in the introduction to the formulary should explain that the presence or absence of a trade name does not imply that it is or is not the agent stocked by the pharmacy.
- **Dosage form, strength, and size stocked by the pharmacy**
- **Active ingredients (formulation) for combination products**

Additional information that may be added:

- **DEA schedule (C-II through C-V)**
- **Special precautions** — Such as for intramuscular (IM) use only and protect from light.
- **Pediatric or adult dosage ranges**
- **Cost information** — Some health systems have chosen not to publish actual purchase prices for confidentiality reasons but rather to list a cost scale to allow for price comparisons. Cost information is most useful when drugs are arranged within a therapeutic group or class to allow for easy comparison.

The medication list should include one or more indexes. The index should assist the user in locating the medication entry by generic name and should include both generic and trade name entries. The trade name entry may state “see generic name, page 123.” Such an index may be incorporated into the formulary itself. If that is done, then the formulary listing should be alphabetical and include both generic and trade names.

A second index type is the therapeutic index. This index arranges drugs generically by therapeutic or pharmacologic class. It is particularly useful for the prescriber who is not familiar with the formulary of a health system and desires to prescribe a certain type of drug (i.e., ACE [angiotensin-converting enzyme] inhibitor).

Medication-Use Policy and Procedures

Inclusion of information on the prescribing, dispensing, and administration of medications in the published formulary provides a quick reference for healthcare providers. Either selected policies may be published or key information summarized in an abbreviated format. Policies for inclusion are the formulary policy, P&T committee policy, and organizational regulations regarding medication use. Information on pharmacy operating procedures may be beneficial. These would include hours of services, prescription policies, medication distribution procedures, contact information, and other pharmacy services such as anticoagulation monitoring or pharmacy newsletters.

Medication-Use Guidelines

This section should detail guidelines for medication use, which are approved or endorsed by the P&T committee. Such guidelines may include preprinted orders and clinical pathways that have been developed. Examples of medication-use guidelines include the following:

- Antibiotic use guidelines
- Antibiotic use in surgical prophylaxis
- Community-acquired pneumonia clinical pathway
- Weight-based heparin orders
- Potassium replacement orders
- Intensive care unit (ICU) sedation guidelines

- Thrombolytic therapy guidelines for stroke
- Alcohol detoxification orders

Special Information

The information in this section is health-system specific. It should be tailored to the needs of the professional and medical staff based on the services provided by the health-system and the pharmacy. Examples of topics to include are as follows:

- Nutritional products approved for use
- Equivalent dosage tables (e.g., pain medications, corticosteroids)
- Parenteral nutrition formulas
- Pediatric dosages
- Potassium content of drugs or foods
- Antidote list
- Advanced cardiac life support (ACLS) or emergency medication list and dosages
- Metric conversion table
- Serum drug levels
- Standard concentrations of drugs in IV solutions
- Common equations used (e.g., ideal body weight, estimated creatinine clearance, anion gap)
- Antibigrams
- Drug dosing in renal or hepatic dysfunction
- Examples of forms that are routinely used (e.g., nonformulary drug requests, adverse drug reaction reports)

Publishing the Formulary

The formulary must be published regularly. The medication list should be readily available to all personnel involved in the medication process. Electronic versions of the formulary may be preferable. Copies of the formulary should be made available where medications are prescribed, administered, and dispensed. Formularies may be printed or electronic; electronic versions posted on the health-system network are preferred. A method should be established for updating the formulary frequently and on an ongoing basis.



SUMMARY

The pharmacist plays a critical role in the management of medication use in the health system. As the drug expert, the pharmacist can assure safe, efficacious, and cost-effective drug use through the formulary system. Ongoing formulary maintenance and routine DUEs are key elements in this process. Focused consideration of medication safety in all medication-related discussions optimizes formulary system management.

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CHAPTER REVIEW QUESTIONS

1. The following elements of the formulary system are used to manage drug costs.

- a. Therapeutic interchange
- b. Nonformulary drug use
- c. Generic substitution
- d. Drug therapy guidelines

Answers: a, c, d. Nonformulary drug use often drives up drug costs in a health system.

2. The formulary must be published and made available to all members of the hospital.

- a. True
- b. False

Answer: a. True. The formulary must be published in paper or electronic format and continually updated as changes occur.

3. P&T committees may have subcommittees to facilitate specific objectives. Examples of subcommittees include which of the following?

- a. Medication Safety
- b. Antimicrobial Stewardship
- c. Formulary Review

Answers: a, b, c. All are potential working subcommittees of a P&T committee. Formulary review committees often do the due diligence for formulary decisions prior to P&T committee consideration.

4. When selecting a drug for formulary addition, which of the following should be considered?

- a. What is the cost of the medication?
- b. Is it a duplication of an existing formulary agent?
- c. How should it be used?
- d. Is it safer than similar agents already on formulary?
- e. Is the drug stocked at nearby hospitals

Answers: a, b, c, d.

5. The _____ is responsible for oversight of all medication use in the hospital.

Answer: P&T committee

6. Therapeutic interchange _____.

- a. Is the interchange of generic equivalents.
- b. Is the interchange of chemically different drugs within the same pharmacologic or therapeutic class.
- c. May be done only in accordance with approved written guidelines.
- d. FDA-approved interchanges are listed in the *Orange Book*.

Answers: b, c. Therapeutic interchange must be approved prior to implementation.

7. **Medication-use evaluation is a systematic approach to monitoring drug therapy and associated outcomes. The optimal data collection period is _____.**

Answer: Concurrent or during the patient visit.

8. **The P&T committee is a multidisciplinary committee including physicians, pharmacists, and nurses.**
- True
 - False

Answer: a. True. Although pharmacists and nurses may not be permitted to vote, they are important members of the committee.

9. **The rationale for completing a DUE is to _____.**
- Validate that drug use is safe and appropriate.
 - Determine the most common prescribers of a specific drug.
 - Educate the nursing staff on appropriate medication administration.

Answer: a. DUE monitoring criteria often include indication for use and adverse events as well as other criteria such as dose, frequency, and route of administration.

10. **The pharmacist is NOT responsible for ensuring the following:**
- Quality, quantity, and source of all medications in the health system.
 - All medications in the health system meet FDA and USP standards.
 - All brands of formulary agents are available for use in the health system.

Answer: c. Formulary systems seek to reduce the number of brands of medication because offering all brands is inefficient and costly.

CHAPTER DISCUSSION QUESTIONS

- How do formularies influence safe medication use within institutions?
- How can pharmacists take a leadership role in the formulary management?
- What are key elements in successful and efficient operation of a P&T committee?
- How can medication-use guidelines facilitate optimal drug use and impact the formulary management process?

Clinical Pharmacy

John E. Murphy



LEARNING OBJECTIVES

After completing this chapter, readers should be able to:

1. Discuss different perspectives on the activities and practice of clinical pharmacy.
2. Contrast clinical pharmacy services with distributive pharmacy services.
3. Identify common clinical pharmacy services offered in acute and ambulatory care settings.
4. Identify five clinical pharmacy services that are associated with reduced mortality, decreased drug and total cost of care, and reductions in length of stay and medication errors in acute and ambulatory care settings.
5. Advocate for the value of clinical pharmacy services.



KEY TERMS AND DEFINITIONS

- **Board certification:** The process by which a clinician specialist may be recognized as possessing a high level of knowledge about the specialty. The initial recognition is by examination after a period of time practicing or doing a residency in the specialty area. Maintenance of specialty recognition may be done by specific education over time or re-examination. Current specialties recognized by the Board of Pharmacy Specialties (BPS) include ambulatory care, cardiology, critical care, infectious diseases, nuclear, nutrition support, oncology, pediatric, pharmacotherapy, and psychiatric pharmacy. BPS is evaluating whether pain and palliative care, sterile compounding, solid organ transplantation, and emergency medicine should be recognized as pharmacy specialties. It was recently announced that the Certified Geriatric Pharmacist credential is moving to BPS, which will help solidify this specialty among the others.
- **Board of Pharmacy Specialties (BPS):** The board that recognizes, sets standards for, and provides board certification in specific clinical specialties. It oversees the development of specialties and the examinations and continuing education programs for the specialties (<http://www.bpsweb.org/>).
- **Clinical pharmacist:** An individual in any practice setting who provides a substantial amount of direct patient-oriented care with an emphasis on the science and practice of rational drug use.
- **Clinical pharmacy:** The area of pharmacy concerned with the science and practice of rational medication use. It is patient-directed, evidence-based, and designed to promote health, wellness, and disease prevention to improve patients' quality of life.
- **Credentials:** Documented evidence of professional qualifications. For pharmacists, examples of credentials include academic degrees, state licensure, residency program certificate of completion, and board certification in a pharmacy specialty.

- **Evidence-based:** Refers to healthcare decisions that incorporate the best evidence currently available in the scientific literature and systematic study of what works best in patient populations.
- **Fellowship:** A 1- to 3-year research-related experience (usually clinical research) that may contain a small portion of associated clinical practice skill development.
- **Joint Commission of Pharmacy Practitioners (JCPP):** A federation of 11 major organizations in the United States that influences pharmacists and pharmacy practice.
- **Postgraduate year 1 (PGY1) residency:** Residencies that are general in nature and provide the opportunity to accelerate a pharmacist's growth beyond entry-level professional competence in patient-centered care and in pharmacy operational services, and to further the development of leadership skills that can be applied in any position and practice setting. "PGY1 residents acquire substantial knowledge required for skillful problem solving, refine their problem-solving strategies, strengthen their professional values and attitudes, and advance the growth of their clinical judgment."¹
- **Postgraduate year 2 (PGY2) residency:** Residencies that are more specialized in nature and prepare the resident to focus in a particular area of practice or take care of particular types of patients. PGY2 residencies are designed to develop accountability; practice patterns; habits; and expert knowledge, skills, attitudes, and abilities in the respective advanced area of pharmacy practice. Completion of a PGY2 program should help prepare the resident for board certification in the specialty practice area, when board certification for the area exists.
- **Residency:** An organized and directed postgraduate training experience of 1 to 2 years' duration that serves as a bridge between education and practice. The resident is exposed to key areas of practice where they will increasingly take responsibility for the care of patients. They also will focus on learning about the medication-use system at the residency site.



INTRODUCTION

The pharmacy profession has long been evolving its various roles of delivering care to patients. Throughout history the profession has been associated with the delivery of medications as one of its primary values for patients in need of these therapies. However, the profession occasionally restricted its role in the process. For example, as late as 1969, the American Pharmacists Association's Code of Ethics stated that pharmacists "should never discuss the therapeutic edict of a Physician's prescription with a patron or disclose details of composition." As the preparation of medications moved from individual pharmacists to the pharmaceutical industry, and dispensing processes became functions that pharmacy technicians and technology could handle well, pharmacists have continually evaluated their purpose and evolved in their optimal roles in patient care.

As early as the 1950s, health-system pharmacy pioneers were advocating that pharmacists go to patient care areas and create a clinical role, including rounding with physicians.² These individual pioneers of clinical pharmacy were driven to encourage and enable pharmacists to use their drug knowledge in the clinical care of patients.³ By the 1970s and 1980s, pharmacists in health-system settings were creating many new clinical roles. Pharmacy organizations began creating policies and activities to enhance the clinical skills of their members and also encouraged the colleges and schools of pharmacy to train their students

to become clinicians, something many resisted adopting or even fought against. Thus, creating cross-cutting change required the development of consensus. As momentum built for change, various organizations sought ways to coordinate thought about the new directions. For example, the American Society of Health-System Pharmacists (ASHP; then the American Society of Hospital Pharmacists) held a conference called Directions for Clinical Practice in Pharmacy in 1985 on Hilton Head Island in South Carolina that helped galvanize thinking about the clinical future of the profession.

KEY POINT . . .

The move toward training all pharmacists to take on clinical roles is something that was opposed by many individuals inside and outside of the profession.

. . . SO WHAT?

It is easy to take for granted today the opportunities available for pharmacists in clinical practice. However, many pharmacists and others fought for years against the move toward a clinical practice model. Indeed, there are still pharmacists today who resist accepting substantial clinical roles.

WHAT IS CLINICAL PHARMACY?

“It’s the Patient, Stupid”

When former U.S. President Bill Clinton was first running for office, it was reported that a sign was prominently placed in his campaign headquarters stating “It’s the economy, stupid!” to keep him focused on the most important issue to the American people at the time. When it is time to consider what clinical pharmacy is or isn’t, staying laser-focused on why pharmacy and the health professions exist can be simply stated, “It’s the patient.” We exist to serve them well. Many have defined **clinical pharmacy** over the years, including the American College of Clinical Pharmacy (ACCP), which has done so in simple abridged fashion as “the area of pharmacy concerned with the science and practice of rational medication use.”⁴ Others have called it, “the concept of a patient-oriented rather than a drug product-oriented pharmacy practitioner.”⁵ ACCP further states that **clinical pharmacists** “provide patient care that optimizes medication therapy and promotes health, wellness, and disease prevention.”⁴ They also provide a more detailed unabridged definition that focuses on (1) the discipline of clinical pharmacy, (2) the clinical pharmacist, and (3) the roles of the clinical pharmacist. These three areas will be discussed in greater detail in this chapter.

ACCP and ASHP have developed many documents describing the competencies and training necessary to provide clinical pharmacy services (direct patient care), including the necessity for residency training and the vision that pharmacists will increasingly become board certified if they provide direct patient care in specialty areas.⁶⁻¹⁰

The **Joint Commission of Pharmacy Practitioners (JCPP)**, a forum for the chief executive and chief elected officers of the 11 premier national pharmacy organizations, approved its Vision for Pharmacist’s Practice in 2014.¹¹ That vision was: “Patients achieve optimal health and medication outcomes with pharmacists as essential and accountable providers within patient-centered, team-based healthcare.” They further provided responsibilities for pharmacists that included:

the rational, evidence-based use of medications; facilitating achievement of patients’ health and medication-related goals; the promotion of wellness, health improvement, and disease prevention; the design and oversight of safe, accurate, and timely

*medication distribution systems; and the provision of high-quality, compassionate, cost-effective care.*¹¹

These are clearly clinical pharmacy functions that are unrelated to dispensing (other than oversight).

The ultimate goal of clinical pharmacy should be that “every patient who needs the clinical drug knowledge and skill of the pharmacist does in fact receive the services.”⁹ This is not the case in many practice settings. Although progress has surely been made, some suggest that little real change has occurred in the profession despite the great need that exists.¹² Because medication therapy has become a critical component of healthcare, the need for medication therapy experts is acute. ASHP stated in their long-range vision for the pharmacy work force that “Medication use in hospitals and health systems is a prominent therapy for virtually all patients, and it is inherently complex and dangerous.”¹⁰ Clearly this is also the case for many patients on multiple medications in all settings who are virtually on their own when it comes to understanding their drug therapy. Clinical pharmacists have the education and training to help these patients when given the opportunity.

As clinical pharmacy developed over the years, some pharmacy leaders began to suggest that it was “a reactive service supplied on the request of physicians for physicians,” rather than direct care for the patients themselves.¹³ This, in part, led to the redefining concept of pharmaceutical care as the “responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient’s quality of life.”¹⁴ *Pharmaceutical care* later transformed to *pharmacy care* in the lexicon of several pharmacy organizations. Pharmacy care is essentially a rebranding of the pharmaceutical care concepts to focus on pharmacy rather than pharmaceuticals, because the proponents of pharmaceutical care indicated that the services could be provided by many healthcare providers.¹⁵ In truth, all of these terms and the functions describe the role of pharmacists in ensuring optimal outcomes for patients through rational drug therapy, which is the ideal of clinical pharmacy practice.¹³

KEY POINT . . .

Clinical pharmacy is patient-oriented rather than drug product-oriented.

. . . SO WHAT?

The pharmacy profession has attempted to move from an orientation toward a thing (i.e., drug) to a focus on a person (i.e., the patient). This reorientation has been slow for a number of reasons. *One*, pharmacists are the only professionals uniquely associated with medications, and the effective distribution of drugs requires extensive and vital efforts without taking on other responsibilities. *Two*, payment for pharmacist services revolves around the dispensing of drugs—not managing the impact of those drugs on patient health outcomes. Thus, that which gets paid for gets accomplished. *Three*, barriers in healthcare still exist toward pharmacists having greater patient orientation: antiquated laws, perceptions of the public, inadequate use of new technology, and the structure and financing of the healthcare system.

THE DISCIPLINE AND THE PROCESS

As members of a health science discipline, clinical pharmacists optimize medication therapy and promote health, wellness, and disease prevention. Further, the discipline embraces

pharmaceutical care by blending “a caring orientation with specialized therapeutic knowledge, experience, and judgment for the purpose of ensuring optimal patient outcomes.”²²

Evidence-Based Process

Determining the best use of medications for individuals and populations must be **evidence-based** because guidelines for performance improvement have been shown to improve patient care outcomes.¹⁶ Clinical pharmacists have long provided valuable services to health-care teams and individuals through analysis of the literature and development of treatment guidelines, and a number of pharmacy organizations have created policies promoting the pharmacist’s role in these processes. An example of this comes from the American Pharmacists Association (APhA). APhA states that pharmacists should be directly involved in developing, evaluating, and implementing clinical guidelines for diseases. They further suggest that guidelines can promote interprofessional team approaches to patient care where pharmacists’ expertise in optimizing patient outcomes can be used. APhA also believes that clinical guidelines should be developed using interprofessional approaches and be built on the best scientific data that are evaluated regularly to ensure the guidelines reflect current practice standards.¹⁷ The latter is an important consideration because new knowledge can, on occasion, substantially change the thinking about how patients should be treated for a given disease. Thus, clinical pharmacists must commit to lifelong learning and frequent assessment of the literature to ensure that treatment approaches remain the best possible for patients. A 2013 survey indicated 77% of responding hospitals use clinical practice guidelines that included medications, indicating a continuing role for pharmacists in this arena.¹⁸

Another example of an organization promoting the value and role of pharmacists in developing and applying evidence-based approaches is ASHP’s 2015 Initiative, which stated that pharmacists in hospitals “will apply their time to direct, interdisciplinary patient care to ensure the best use of medicines by individual patients” and that “the objective of the overall pharmacy function in hospitals and health systems is to support sound patient care through the safe, evidence-based, and cost-beneficial use of medicines.”¹⁹

Developing evidence-based guidelines and ensuring their use provides outstanding opportunities for clinical pharmacists to impact large numbers of patients in all healthcare delivery settings.

Therapeutic Problem-Solving Processes

Clinicians generally follow mostly standard processes to evaluate patients, determine appropriate treatments, and document the findings in patient charts. Common approaches in pharmacy have been SOAP (**S**ubjective findings, **O**bjective findings, **A**ssessment, and **P**lan) and FARM (**F**indings, **A**ssessment, **R**ecommendations, and **M**onitoring) notes. Other approaches have also been suggested for pharmacists to organize their evaluation of patients. For example, the Clinical Pharmacist Recommendation (CPR) Taxonomy was developed for pharmacists’ clinical use and also to compare clinical pharmacy intervention trials.²⁰ Another approach, the Pharmacists’ Management of Drug-Related Problems (PMDRP), was designed to reduce variation in monitoring forms and to focus specifically on the identification and management of drug-related problems.²¹ The JCPP approved the Pharmacists’ Patient Care Process in 2014,²² and the Accreditation Council for Pharmacy Education (ACPE) incorporated the process as part of teaching requirements in the 2016 accreditation standards for colleges and schools of pharmacy. The process is as follows:

- **Collect** — subjective and objective information
- **Assess** — the information relative to an individual

- **Plan** — an individualized patient care plan
- **Implement** — in cooperation with other providers and the patient or caregiver
- **Follow-up: monitor and evaluate** — monitor and modify as needed

All of these methods serve to consistently organize a clinician's evaluation of a patient and each allows for similar information to be incorporated, although under slightly different headings. No matter which rubrics are used, there is value in consistency of approach across the profession to help ensure patients receive similar clinical services.

THE CLINICAL PHARMACIST

Competencies

The clinical pharmacist is a highly educated and well-trained individual, with specialized knowledge and experience, who contributes to the outcomes of patients by using this knowledge to enhance drug therapy. In addition to the development of specific competencies, clinical pharmacists must be dedicated to lifelong learning to ensure their value to the interprofessional healthcare team. Specific competencies and roles of the clinical pharmacist have been outlined in a number of publications and in policies and guidelines of various pharmacy organizations. For example, the ACCP created a task force to outline the competencies they considered of greatest importance for clinical pharmacists.⁶ A summary of this extensive list is shown in **Table 5-1**.

Education, Training, and Credentials

Over the years, many pioneers in clinical pharmacy honed their skills with on-the-job training and just getting involved; they may or may not have had an advanced degree or residency training prior to beginning their participation. Although this pathway to a career focused on clinical practice clearly remains possible today, the academic and training environment has changed. On the education side, all pharmacists in the United States graduate with a doctor of pharmacy degree that provides more clinical education than ever before. However, medication therapy is becoming increasingly complex as well, particularly in the hospital setting, but also in many ambulatory care practices.

After graduation from pharmacy school, opportunities to advance skills and knowledge exist through continuing professional development programs, postgraduate training (e.g., **residencies** and **fellowships**), and graduate school. Organizations such as ACCP and ASHP stated that all phar-

KEY POINT . . .

Attaining residency training is a well-recognized and accepted path to becoming a clinical pharmacist, although rigorous on-the-job training is still a challenging and possible option. Becoming board certified in one of the pharmacy specialties is a way to demonstrate attainment of the knowledge associated with a direct patient care practice.

. . . SO WHAT?

The automatic answer that many educators and clinical pharmacists provide to students seeking a clinical career is, "Do a residency."

However, this traditional path toward becoming a clinical pharmacist is not the only one, and there remains an undersupply of residency positions relative to demand by graduates. Many clinical pharmacists learned on-the-job: a path requiring exceptional and highly motivated individuals and the support of employers for success.

TABLE 5-1.**Clinical Pharmacist Competencies⁶****I. Clinical problem solving, judgment, and decision making**

- A. Monitor patients in the healthcare setting.
- B. Assess patient-specific medical problems.
- C. Evaluate patient-specific drug therapy and therapeutic problems.
- D. Design a comprehensive drug therapy plan for patient-specific problems.
- E. Collaborate with patients, caregivers, and other healthcare professionals.

II. Communication and education

- A. Educate patients.
- B. Educate other healthcare professionals.
- C. Communicate effectively.
- D. Document interventions in the patient medical record.

III. Medical information evaluation and management

- A. Demonstrate the motivation and commitment to become a lifelong learner.
- B. Retrieve biomedical literature using appropriate search strategies.
- C. Interpret biomedical literature with regard to study design, methodology, statistical analysis, significance of reported data, and conclusions.
- D. Integrate data obtained from multiple sources to derive an overall conclusion or answer.

IV. Management of patient populations

- A. Evaluate patient safety and drug therapy.
- B. Develop critical pathways.

V. Therapeutic knowledge areas

- A. Apply disease-oriented knowledge of the following areas (various areas provided in document—e.g., anatomy, epidemiology, prognosis, interpretation of laboratory tests).
- B. Demonstrate competence in the pharmacotherapy of the following medical problems (various areas provided in document—e.g., categories include bone and joint, cardiovascular, dermatologic, endocrine, infectious diseases; subcategories appear under each).
- C. Apply the following principles in the setting of each disease state, patient population, and/or therapeutic category (e.g., pharmacokinetics, pharmacogenomics, health screening, drug interactions, immunizations, considerations for geriatrics and pediatrics).

Additional details of competencies are provided under each subcategory.

macy students planning to provide *direct patient care clinical services* should be adding **postgraduate year 1 (PGY1) residency** training to their credentials.^{8,23} The organizations realized that some graduates would pursue other opportunities that would not require the extensive clinical education and training provided by a residency, such as graduate school in a basic science discipline or business school. ACCP also suggested that most clinical faculty should have a **postgraduate year 2 (PGY2) residency** as might clinicians practicing in specialty areas of the healthcare system. Some clinical pharmacists will also desire to advance their research skills and may pursue graduate degrees or fellowships, particularly if they are interested in an academic or industry position with research as an essential component.

In addition to the education and training credentials available to individuals, increasing numbers of specialist pharmacists seek to demonstrate their knowledge through **board certification**. These **credentials** can enhance an individual's ability to gain clinical privi-

leges to provide patient care services. In addition, purchasers of clinical pharmacy services will increasingly recognize board certification. The issues of credentialing and privileging for pharmacists have been articulated in two papers that are worth reading by anyone interested in the processes and terminology.^{24,25} Both ACCP and ASHP

have stated that most clinical pharmacists providing direct patient care in specialty areas will be board certified in the future.^{9,10} Pharmacy students should learn about the **Board of Pharmaceutical Specialties (BPS)** and the processes for attaining specialty certification to determine the value that such certification might provide for them (see <http://www.bpsweb.org/>).

Pharmacy graduates who don't have the opportunity to enter a residency can develop clinical skills over time and demonstrate achievement of the knowledge by becoming board certified in one of the BPS' pharmacy specialties. Ambulatory care and pharmacotherapy are the more crosscutting specialties requiring high-level knowledge in many areas of practice.

KEY POINT . . .

Both ACCP and ASHP have stated that most clinical pharmacists providing direct patient care in specialty areas will be board certified in the future.

. . . SO WHAT?

As the profession evolves, requirements for practice will evolve too. The trend in clinical practice is an expectation that clinical specialists become board certified. New pharmacists should consider board certification as one way to differentiate themselves for future clinical positions.

ROLES

A wide variety of activities is associated with clinical pharmacy practice. Bond and Raehl evaluated associations of clinical pharmacy services and level of pharmacy staffing with reductions in hospital mortality rates.^{26,27} The services evaluated and the percent of responding hospitals offering the services at the time included drug-use evaluation (94.5%), pharmacokinetic consultations (80.3%), adverse drug reaction management (70.4%), drug protocol management (69.6%), in-service education (65.5%), drug therapy monitoring (53.5%), drug therapy counseling (46.3%), total parenteral nutrition (TPN) team participation (43.6%), participation on cardiopulmonary resuscitation team (31.8%), drug information services (25.7%), participation on medical rounds (22.9%), poison information (15.5%), clinical research (11.8%), and the taking of admission drug histories (4.2%).²⁶ In more recent survey results, Pedersen and colleagues noted a high level of pharmacists' consulting activity in responding hospitals including dosage adjustment (98%), drug information (93%), antibiotic therapy recommendations (92%), and pharmacokinetics (92%).¹⁸

Pharmacokinetic consultations can be used as an example of growth and evolution of a clinical service over time as well as an indicator of the types of medications for which pharmacists are providing consultations, since pharmacists have been active in providing pharmacokinetic consultations for a long time. In the early days of these services, hospitals may have had specific dosing services with pharmacokinetics specialists; now clinical pharmacy staff in the institutions provide most of the consults.²⁸ These pharmacy-directed services were provided in 86.8% of hospitals responding to a 2006 survey, a 117.5% increase from an earlier survey in 1989.²⁹ In 2012, Pedersen and colleagues found that pharmacists monitor most patients (i.e., >75%) in 46.5% of hospitals responding to a survey, an increase from 20.3% in 2000. Most hospitals provided therapeutic drug monitoring programs, and pharmacists had the authority to order laboratory tests and adjust medication dosages at more than 80% of responding hospitals.³⁰ All of these longitudinal studies demonstrate that provision of clinical services is increasing over time.

When Bond and Raehl combined their previous study data, they found five key clinical pharmacist services that were associated with reductions in patient mortality, decreased drug and total cost of care, and reductions in length of stay and medication errors.³¹ The authors recommended that the profession provide these services to increase the potential for recognition as healthcare providers. The five services were:

1. Drug information
2. Adverse drug reaction management
3. Drug protocol management
4. Participation in medical rounds
5. Admission drug histories

In their earlier work, Bond and Raehl found that the number of clinical pharmacists and pharmacy administrators per 100 occupied beds was also associated with reduced mortality rates.²⁶ This is an indicator of the value of managing and providing clinical services.

OTHER CLINICAL PHARMACY SERVICES

Pharmacists have been involved in many innovative clinical services over time. In September 2016, a PubMed literature search of publications using the term *role of the pharmacist* yielded 5,614 references. This is an indicator of efforts by pharmacists to create new, primarily clinical roles. Some roles described in the literature include (1) caring for patients with diabetes; patients with chronic renal failure; patients in prisons; and patients with hypertension, hyperlipidemia, and migraine and (2) providing medication therapy management services. Some other important clinical services include the following:

- **Medication reconciliation** — Pharmacists or other health professionals provide medication reconciliation services in response to the understanding that medication errors occur too frequently when patients are transferred from one setting to another, and medications are added or deleted without determining whether they are needed or not. The Joint Commission established medication reconciliation as an important quality service for hospitals, and pharmacists increasingly provide these reviews.
- **Education** — Though education, per se, is not solely a clinical service, institutions associated with educating pharmacy students generally provide more clinical pharmacy services than institutions that do not.³¹
- **Collaborative practice** — Laws and regulations permitting collaborative practice arrangements between pharmacists and prescribers have been enacted in at least 48 states and the District of Columbia. These arrangements allow pharmacists to control the medication therapy of specified patients and sometimes specified diseases in collaboration with one or more prescribers.
- **Immunizations** — Administration of an injection should probably not be considered a clinical pharmacy service, although it does put the pharmacist in physical contact with a patient and can enhance the perception of pharmacists' ability to provide other patient care services. Conversely, determining a patient's need for an immunization and setting up a tracking and reminder program to ensure that patients are immunized would be a clinical service.
- **Primary care** — Pharmacists have opportunities to participate in providing primary patient care services in ambulatory care settings. These are most often done as part of collaborative practice in a setting where access to patient data is easiest. As electronic medical records are more readily available, access may become more

virtual (i.e., electronically) than site-dependent, creating new opportunities for collaboration of pharmacists and primary care providers and the potential to become independent prescribers. With more patients insured through the Affordable Care Act, which hopefully will continue with revisions to the Act, additional opportunities to provide primary care may well develop for pharmacists.

- **Identifying and resolving drug-related problems in population-based care** — Clinical pharmacists provide valuable population-based care through the development and enforcement of guidelines in managed care settings. Medication therapy management programs provided to large groups of patients also offer these opportunities.
- **Designing systems that prevent drug-related problems at the individual and population level** — Many pharmacists are involved as medication safety officers or as members of medication safety teams in acute and ambulatory care settings, developing programs designed to identify and prevent drug problems for both individual patients and groups of patients.

CONTRASTING CLINICAL AND DISTRIBUTIONAL ACTIVITIES

Clinical and drug distribution services are distinct but complementary activities in ensuring safe medication use. Medication distribution to patients attempts to ensure that the correct physical product gets to each patient. However, important clinical opportunities exist at the point of patient medication distribution to reduce medication problems and enhance the potential for the medications to be beneficial. These include, among other possibilities, determining that the medication is appropriate for the patient (e.g., avoidance of serious drug-drug interactions or allergies, correct dose) and ensuring that the patient or their caregiver understands the instructions for the medication's safe and effective use. The actual technical functions that make up the distribution process, such as determining the medication ordered and instructions for use, creating a label, and preparing the medication in an appropriate container, are activities that do not require a pharmacist's clinical skills and knowledge. Although it is abundantly clear that distribution systems must be safe so that patients do not get the wrong medications or incorrect doses of medication, and pharmacists should ensure that these processes work correctly, pharmacists should have limited involvement with these technical aspects of the process as they can be appropriately done by well-trained technicians and by technology.

KEY POINT . . .

Clinical and drug distribution services are distinct but complementary activities in ensuring safe medication use.

. . . SO WHAT?

The patient-centered integrated model of practice described in Chapter 1 of this text recognizes the responsibility of pharmacists for clinical and distributional roles because of the realization that both are essential for managing the medication-use process. Clinical practice relies on an efficient, well-run distribution system, while getting the right drug in the right dose to the right patient at the right time via the right route of administration relies on good clinical services.

A review of controlled studies that included evaluation of comprehensive patient counseling services by pharmacists at discharge or at the time of dispensing demonstrated that these services led to improved patient outcomes.³² Unfortunately, such comprehen-

sive services or even cursory instructions for use are not consistently provided to patients who may need them. As an example, a chain pharmacy business paid more than \$500,000 in 2015 to settle a consumer protection lawsuit alleging that their pharmacists frequently failed to comply with patient consultation rules. Elizabeth Flynn and colleagues' research showed that pharmacists in community settings automatically counseled fewer than a third of patients when receiving new prescriptions for medications whose misuse could lead to harm.³³ Of interest in this study, pharmacist counseling was unrelated to the busyness of the store.

This highlights a problem with the current dispensing processes—pharmacists are not providing even minimal discussions that patients may need about medications. Indeed, this problem has existed for decades. More than 30 years ago, Russell Miller said that dispensing-oriented practices led to the “frustration of many pharmacists who had completed five or more years of difficult studies only to enter a rather undemanding, unprofessional practice.”³⁵ Unfortunately, the same can be said today for much of the dispensing-oriented practices in too many pharmacy settings. Even worse, another year of training is now associated with getting a pharmacy degree. It is clear that pharmacy must make the full transition to clinical practice. Graduating pharmacy students are too highly trained to be limited to only dispensing medications, and it is hard to justify to employers the high salaries of pharmacists if their skills are underutilized by providing routine dispensing tasks.

One of the most important areas for clinical pharmacy service provision lies in identifying and resolving drug-related problems in direct patient care in all patient care settings. Research has shown the extensive incidence of drug-related problems that can lead to morbidity and mortality as well as huge economic burden.³⁴⁻³⁶ Because many studies have demonstrated that pharmacists providing clinical services directly to patients can decrease these problems, it is unfortunate that such services are not consistently provided, while routine technical functions continue to dominate the practice of many pharmacists.^{26,27,29,37}

Payment for clinical services and recognition as healthcare providers are important criteria for the advancement of clinical pharmacy. When (or if) payment for clinical pharmacy services (either directly for the service or in the hiring of pharmacists to provide them consistently) becomes the norm in all settings, there will be better justification for pharmacists to move from the tasks of medication dispensing to the provision of clinical pharmacy services. When this occurs, patients and payers will be better served.

EVIDENCE OF THE VALUE OF CLINICAL PHARMACY

Numerous studies have been conducted and published examining the outcomes of clinical pharmacy services, although the majority were not designed in a manner that could yield convincing results. Still, several reviews have evaluated appropriately designed studies that documented both the economic and patient care outcome value of clinical pharmacist services.³⁸⁻⁴⁴ One group of researchers evaluated two decades of evidence establishing the association between clinical services in hospital settings with important patient outcomes.^{26,27,29,45,46} Their work showed that

KEY POINT . . .

Change in pharmacy practice will occur only when pharmacists actively lobby stakeholders about the benefits of the medication therapy expertise of clinical pharmacists.

. . . SO WHAT?

Currently, many pharmacists do not advocate for change in pharmacy practice. Nevertheless, the collective effort of the more than 295,000 practicing pharmacists in the United States could make things happen.

core services not only save money but enhance patient outcomes. The task that remains for the profession is to convince key stakeholders (e.g., hospital administrators, insurers, other payers) that clinical services should be provided in all hospitals.⁴⁷ This will occur only when pharmacists actively lobby stakeholders about the benefits of the medication therapy expertise of clinical pharmacists.



SUMMARY

Clinical pharmacy is a patient-oriented, evidence-based practice that uses the medication-related expertise of pharmacists to enhance patient outcomes and improve quality of life, increasingly as part of interprofessional teams. Hallmarks of a patient-oriented clinical pharmacy practice include focusing on the patient, taking responsibility for medication therapy outcomes, and identifying and preventing medication errors and preventable adverse drug events. Although important, services related to the product-oriented dispensing process such as determining the drug name, providing correct directions for use, and placing the medication in an appropriate container for use cannot be classified as clinical pharmacy services. Neither is determining formulary status of the medication to ensure reimbursement and providing simple directions on use (e.g., take twice daily until gone and refrigerate).

Clinical pharmacists provide patient care that optimizes medication therapy and promotes health, wellness, and disease prevention to improve the lives of patients.

Five clinical pharmacy services have been shown to be associated with reductions in patient mortality, decreased drug and total cost of care, and reductions in length of stay and medication errors: drug information, adverse drug reaction management, drug protocol management, participation in medical rounds, and admission drug histories.

The value of certain clinical pharmacy services has been demonstrated in a number of studies, and patients deserve to have the expertise of clinical pharmacists as participants in their treatment. To accomplish this, pharmacists need to move their focus away from dispensing-related activities that can be managed by technology and well-trained technicians. Direct payment for clinical services or the hiring of pharmacists to provide these patient-oriented services is necessary to accomplish this goal, and the profession must continue to advocate for these changes to optimally benefit the patients it serves.

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CHAPTER REVIEW QUESTIONS

1. Which of the following pharmacist-provided services were NOT associated with reduced patient mortality in the hospital setting?

- a. Pharmacokinetic consultation
- b. Adverse drug reaction management
- c. Drug protocol management
- d. Total parenteral nutrition (TPN) team participation
- e. Medical rounds participation

Answer: a and d. A study by Bond and Raehl was unable to find an association between reduced mortality and pharmacokinetic consults or participation on TPN teams.

2. What is the approximate percentage of patients receiving an offer to counsel on new prescriptions in community pharmacies?

- a. 67%
- b. 50%
- c. 40%
- d. 33%

Answer: d. A study by Flynn and colleagues found that fewer than one third of patients with a new prescription received an offer to counsel.

3. The likelihood of a patient receiving an offer to counsel on a new prescription is associated with the busyness of the pharmacy.

- a. True
- b. False

Answer: b. False. According to the study by Flynn and colleagues, an offer to counsel on new prescriptions was unrelated to how busy the pharmacy was at the time.

4. ACCP and ASHP have stated that all pharmacy graduates who intend to provide direct care to patients should undertake a PGY1 residency.

- a. True
- b. False

Answer: a. True. Both organizations have said that all pharmacy graduates who intend to provide direct patient care (clinical) services should plan on a residency. Both organizations also realized that some graduates will have plans that could include graduate school for an MS, PhD, MBA, JD, etc., or to use their pharmacy background outside of direct patient care.

5. **It has been suggested that pharmacists desiring to become clinical faculty should undertake a PGY2 residency and become board certified in an appropriate specialty if one is available.**

- a. True
- b. False

Answer: a. True. ACCP has suggested this need since most clinical faculty practice and teach in specialty rather than general areas. To be effective in their leadership and mentoring of students, these additional credentials are useful. Further, many pharmacists may need to pursue additional research training either before or after taking a faculty position.

6. **Specialty board certification can be achieved by _____.**

- a. Attending specific continuing education programs focused on the specialty topics.
- b. Passing a specialty examination after graduation and passing the NAPLEX exam.
- c. Passing a specialty examination after practicing in the specialty for a specific time period.
- d. a or c

Answer: c. All of the specialties require time in practice in the specialty before taking the exam. This can be achieved in a residency or specialty practice.

7. **Which of the following is most likely to be offered by pharmacists in U.S. hospitals according to data from the papers by Bond et al.?**

- a. Pharmacokinetic consultations
- b. Drug-use evaluation
- c. Participation on medical rounds
- d. Adverse drug reaction management
- e. In-service education

Answer: b. Drug-use evaluation. Bond and Raehl's study in 2007 found these services offered by the following percent of hospitals: drug-use evaluation (94.5%), pharmacokinetic consultations (80.3%), adverse drug reaction management (70.4%), in-service education (65.5%), and participation on medical rounds (22.9%). The studies by Pedersen and colleagues in the *American Journal of Health-System Pharmacy* support these results.

8. **The evidence showing the impact of clinical pharmacy services on economic and clinical outcomes is overwhelming.**

- a. True
- b. False.

Answer: a or b depending on the level of evidence one needs to declare something "overwhelming." Many well-designed trials provide definitive conclusions demonstrating the value of pharmacist services. However, the majority of outcomes research on the impact of pharmacist services have study design limitations that preclude definitive decisions about the value of the services.

9. Which of the following healthcare professionals are NOT recognized as patient care providers by the federal government (for service payment)?
- Pharmacists
 - Podiatrists
 - Nurses
 - Physicians
 - All of the above are recognized

Answer: a. Pharmacists. Although some pharmacists are recognized by certain payers and are paid directly for their services, this is not routine. The federal government does not currently recognize pharmacists as providers, although the profession (via major organizations) instituted major legislative initiatives to change this. A number of states now recognize pharmacists for these roles.

10. There was a time when pharmacists were instructed to “never discuss the therapeutic edict of a physician’s prescription with a patron or disclose details of composition.” Approximately how long ago was this still true?
- 25 years
 - 50 years
 - 75 years
 - 100 years

Answer: b. 50 years. This edict in APhA’s Code of Ethics continued through 1969. Fifteen years later the first patient counseling competition was held for student pharmacists, indicating the complete reversal of such thinking.

CHAPTER DISCUSSION QUESTIONS

- What are the differences between providing basic information about a medication to a patient at the time of dispensing and counseling of a patient to enhance medication outcomes?
- What should individual pharmacists do to help promote the value of providing direct patient care so that the profession is recognized as a patient care provider?
- What are the greatest barriers to enhanced pharmacist involvement in direct patient care activities in community and hospital settings?

Medication Safety

David A. Holdford

LEARNING OBJECTIVES

After completing this chapter, readers should be able to:

1. Describe the extent of medical errors in the U.S. healthcare system.
2. Define key terms in medication safety.
3. Describe and classify various medication errors.
4. Identify potential causes for medication errors.
5. List strategies for improving medication safety in health-system pharmacy practice.

KEY TERMS AND DEFINITIONS

- **Administration error:** An incorrect medication administration that includes the wrong dose, omitted dose, additional dose, wrong administration time, incorrect handling of drugs during administration, and wrong infusion rate.
- **Adverse drug event (ADE):** An injury, large or small, preventable or unpreventable, that may be caused by the use or lack of intended use of a drug.
- **Adverse drug reaction (ADR):** A drug-related problem that consists of an unexpected, unintended, undesired, or excessive response to a drug that requires some type of medical response (e.g., discontinuing the drug, changing therapy, making major dose modifications) or results in a negative outcome (e.g., hospital admission, prolonged treatment, harm, disability, death). It may or may not be the result of a medication error.
- **Allergic drug reactions:** A type of ADR resulting from immunologic hypersensitivities to drugs.
- **Dispensing error:** A mistake during the dispensing process where a patient receives the wrong drug, the correct drug for the wrong patient, wrong galenic form (e.g., tablet for patient who is NPO [nothing by mouth]), or wrong dose.
- **Drug misadventure:** An iatrogenic hazard or incident associated with indicated drug therapy resulting in patient harm that can be attributable to error, immunologic response, or idiosyncratic response—consisting of the sum of medication errors, ADRs, and ADEs.
- **Drug-related morbidity:** The failure of a drug to achieve its intended health outcome due to unresolved drug-related problems. It is a negative outcome associated with an error.
- **Drug-related problems (DRPs):** Events associated with drug therapies that can or do hamper optimal patient health outcomes.
- **Error of commission:** An error that results when the patient receives the correct drug in a way that does not result in optimal patient outcomes or an incorrect drug, which puts the patient at risk of negative outcomes.
- **Error of omission:** An error that results in a patient failing to receive a beneficial drug.

- **Idiosyncratic reaction:** A type of ADR resulting from abnormal responses to drugs that are peculiar to individuals.
- **Latent injury:** A propensity or predisposition for harm during the process of care that actually does not result in patient injury.
- **Medication error:** Any error in the medication process (prescribing, dispensing, administering of drugs), whether there are adverse consequences or not.
- **Medication reconciliation:** The process of resolving discrepancies as patients transition across departments (e.g., a medical intensive care unit [ICU] to a step down unit), locations (e.g., inpatient to outpatient), or other places.
- **Monitoring error:** The failure to review a prescribed regimen for appropriateness and detection of problems, or failure to use appropriate clinical or laboratory data for adequate assessment of patient response to prescribed therapy.
- **Outcome:** The end result attributable to healthcare products or services such as mortality, infection, myocardial infarction, and pain.
- **Potential adverse drug event:** A mistake in prescribing, dispensing, or medication administration that has the potential to cause an ADE but did not, either by luck or because it was intercepted.
- **Prescribing error:** An incorrect drug, dose, dosage form, quantity, route, concentration, rate of administration, or instructions for use that a prescriber has ordered or authorized. It includes illegible prescriptions or medication orders leading to errors that reach the patient.
- **Process:** Actions associated with quality such as reviewing patient orders prior to dispensing, conducting drug-use evaluation, and counseling patients prior to discharge.
- **Sentinel event:** An unexpected occurrence involving actual or potential death or serious injury. These events signal the need for immediate investigation and response.
- **Side effect:** An expected, well-known reaction resulting in little or no change in patient management (e.g., drowsiness or dry mouth associated with certain antihistamines).
- **Structure:** The presence of something that is reasonably associated with quality such as a pharmacy, a pharmacist, available references, 24-hour pharmacy services, a formulary, and a computerized prescriber order entry system.
- **Transcription and/or interpretation error:** An error in transcribing or interpreting prescriptions due to causes including misinterpretation of abbreviations, illegible hand-written prescriptions, or misinterpretation of spoken prescriptions.
- **Trigger event:** An event occurring during patient treatment that causes a latent injury, which may become an actual discernible injury.



INTRODUCTION

Medication safety has been a priority of health-system pharmacy practice in recent years. Driven by landmark publications including the Institute of Medicine's (IOM) report, *To Err Is Human: Building a Safer Health System*,¹ pharmacists have been attempting to reduce medication risks in institutions. The report highlighted the pervasive nature of injuries associated with both appropriate and inappropriate use of medications—reframing medical error as a chronic threat to public health.¹ Some of the following findings were revealed in the report¹:

- **Medical errors are common** — one medication error per patient per day.
- **Medical errors are tragic** — over 7,000 preventable deaths occur each year due to medication errors.
- **Medical errors are expensive** — resulting in annual costs of \$17–37 billion in the United States due to lost income, disability, and healthcare expenditures.

- **Medical errors are preventable** — at least 400,000 adverse drug events (ADEs) in hospitals are preventable.
- **Medical errors are not fully appreciated** — they cause more deaths each year than breast cancer, motor vehicle accidents, and acquired immunodeficiency syndrome (AIDS).

In a follow-up report, the IOM committee published *Crossing the Quality Chasm: A New Health System for the Twenty-first Century*,² which highlighted the causes of medical errors and called for fundamental changes to improve the quality of healthcare. Since those reports, little evidence has been offered that medication safety has improved.³ This chapter discusses many issues that the IOM identified and their impact in institutional pharmacy settings.

KEY POINT . . .

The IOM concluded that medical errors are common, tragic, expensive, preventable, and not fully appreciated.

. . . SO WHAT?

It is shocking that medical errors are still so common more than a decade after *To Err Is Human*. The public would allow no other industry to put so many people at risks that are so easily preventable.

DEFINITIONS

The terminology of medication safety can be confusing because of the variety of ways of defining and classifying medication errors. This section of the chapter defines key terms and describes various classification systems to give a foundation for subsequent sections on preventing, reporting, and managing medication errors.

Drug-related problems (DRPs) are events associated with drug therapies that can or do hamper optimal patient health outcomes (**Figure 6-1**).^{4,5} DRPs include medication errors, adverse drug reactions, adverse drug events, and side effects. A term very similar to DRPs commonly used in institutional safety studies is *medication misadventures*. Medication misadventures are iatrogenic hazards or incidents associated with indicated drug therapy resulting in patient harm that can be attributable to error, immunologic response, or idiosyncratic response.^{4,6,7} Medication misadventures cover the sum of medication errors and adverse drug events,⁸ as do DRPs, so the two terms will be considered synonymous in this text.

Medication errors are errors or mistakes in the medication-use process (prescribing, dispensing, administering of drugs) that may result in negative outcomes.⁹ Not all DRPs are medication errors because problems in medication use can occur even when best medication practices are applied.

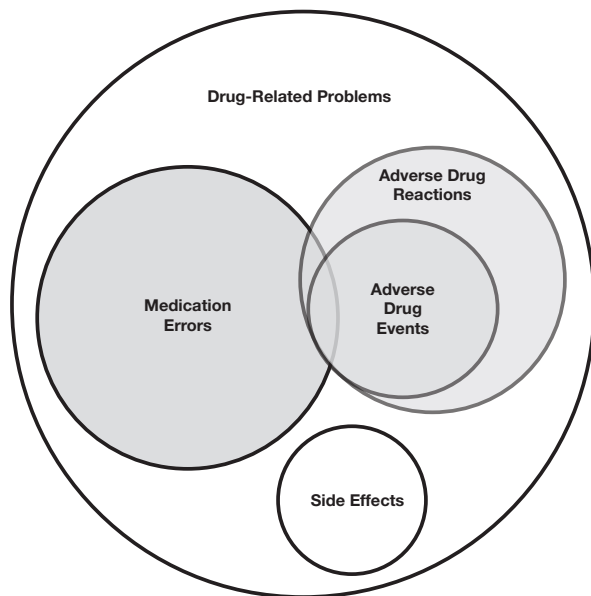


FIGURE 6-1. Various types of drug-related problems.

For example, side effects are DRPs that occur through no one’s mistake—indeed, they are expected, unavoidable reactions of the appropriate use of many drugs (e.g., potential upset stomach associated with nonsteroidal anti-inflammatory drugs). In addition, medication errors may or may not cause adverse consequences, because some mistakes have no negative clinical effects (e.g., a missed dose of blood pressure medicine may not cause any change in blood pressure). In these situations, errors are said to increase only the *risk* of adverse consequence.

Medication errors can be classified in a variety of ways. One way is to classify them by their impact on patients such as illustrated in **Figure 6-2**. This figure shows errors that range from Category A where circumstances have no capacity for harm to Category I where circumstances result in patient death.

Another way is to classify medication errors according to where they exist within the medication-use system (**Figure 6-3**).¹⁰ **Administration errors** occur when patients are administered something other than that prescribed for the patient—the wrong dose, omitted dose, additional dose, wrong administration time, incorrect handling of drugs during administration, or wrong infusion rate. **Dispensing errors** are mistakes made during the dispensing process where a patient receives the wrong drug, the correct drug for the wrong patient, wrong galenic form (e.g., tablet for patient who is NPO), or wrong dose. **Prescribing errors** occur when prescriptions have an incorrect drug selection, dose, dosage form, quantity, route, concentration, rate of administration, or instructions for use of a drug product. These include illegible prescriptions or medication orders leading to errors that reach the patient. **Monitoring errors** result from the failure to review a prescribed regimen for appropriateness or the failure to use appropriate clinical or laboratory data for adequate assessment of patient response to prescribed therapy. **Transcription and/or interpretation errors** are made during the transcribing or interpreting of prescriptions due to causes including misinterpretation of abbreviations, illegible hand-written prescriptions, and misinterpretation of spoken prescriptions.

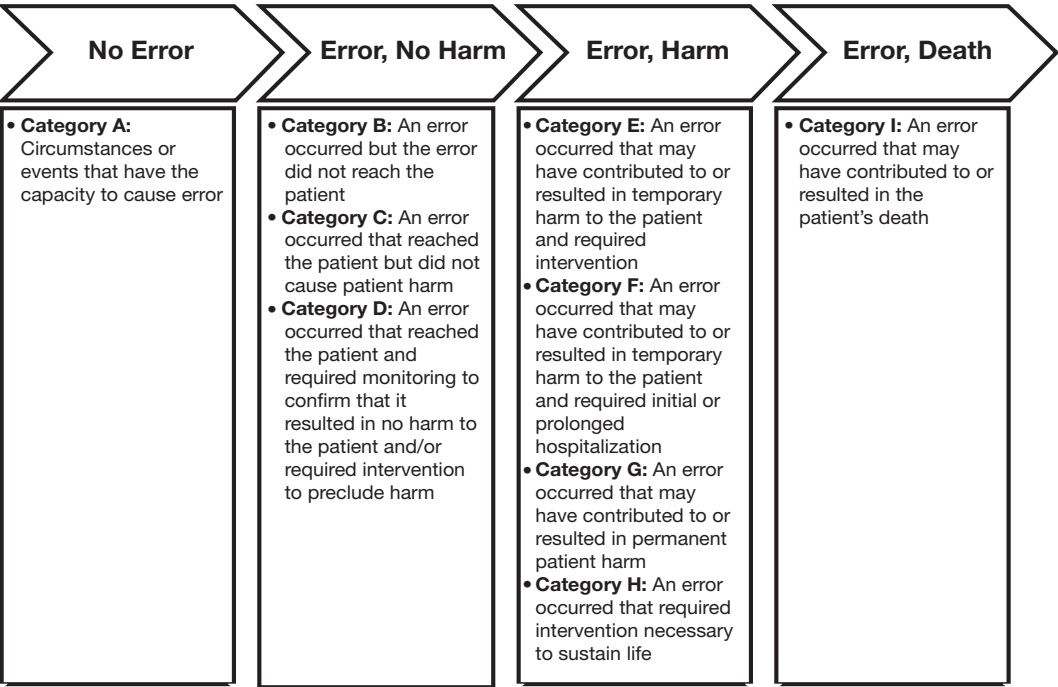


FIGURE 6-2. The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index for Categorizing Medication Errors.¹¹

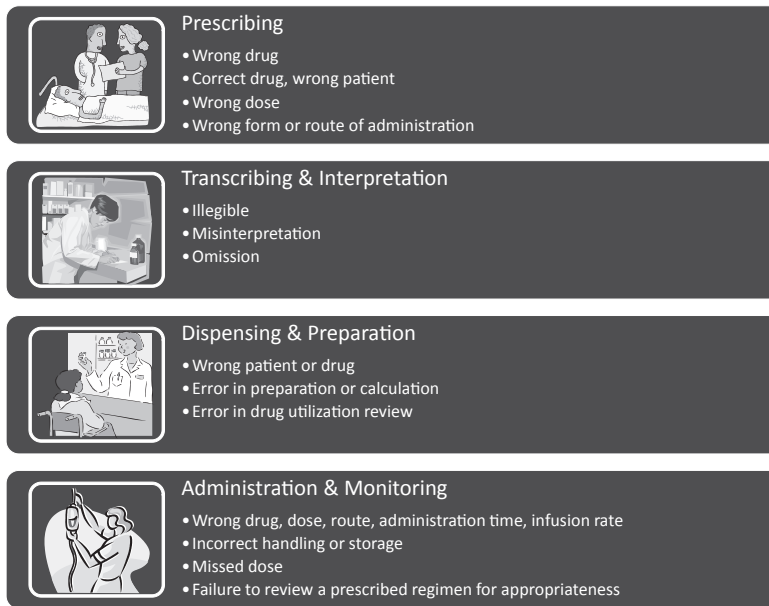


FIGURE 6-3. Consequences of drug-related problems.

Adverse drug reactions (ADRs) are DRPs that are unexpected, unintended, undesired, or excessive responses to a drug that require some type of medical response (e.g., discontinuing the drug, changing therapy, making major dose modifications) or resulting in a negative outcome (e.g., hospital admission, prolonged treatment, harm, disability, death).¹² They may or may not be the result of a medication error. **Allergic reactions** (immunologic hypersensitivities to drugs) and **idiosyncratic reactions** (abnormal responses to drugs that are peculiar to individuals) are considered ADRs.¹² In contrast, **side effects** (expected, well-known reactions that require little or no change in patient management) are *not* ADRs.¹² Neither are other expected, well-known responses such as drug withdrawal symptoms, drug-abuse syndromes, accidental poisonings, and drug-overdose complications.¹² **Adverse drug events (ADEs)** are ADRs that result in an injury—large or small—preventable or unpreventable—due to the use or lack of intended use of a drug.^{4,10} Expected, well-known reactions to medications that are severe enough to require extensive medication management are *not* side effects—they are ADEs.

DRPs associated with errors can have negative outcomes or no negative outcomes (**Figure 6-4**). Any error in the medication-use process can lead to actual or potentially negative health outcomes. Negative outcomes associated with medical errors are called drug-related morbidity. **Drug-related morbidity** is defined as the failure of a drug to achieve its intended health outcome due to unresolved DRPs.^{4,5} **Sentinel events** are unexpected incidents resulting in death or the potential for serious physical or psychological injury. These events are labeled “sentinel” because they signal the need for immediate investigation and response.

In truth, most medication errors do not lead to negative health outcomes. Rather, they elevate the potential for injury associated with drugs. These types of errors are called either *latent* or *potential injuries*. **Latent injuries** are defined as a propensity or predisposition for harm during the process of care that actually does not result in patient injury.⁴ **Potential injuries** are mistakes in prescribing, dispensing, or medication administration that have the potential to cause an injury but did not, either by luck or because they were intercepted.^{4,13}

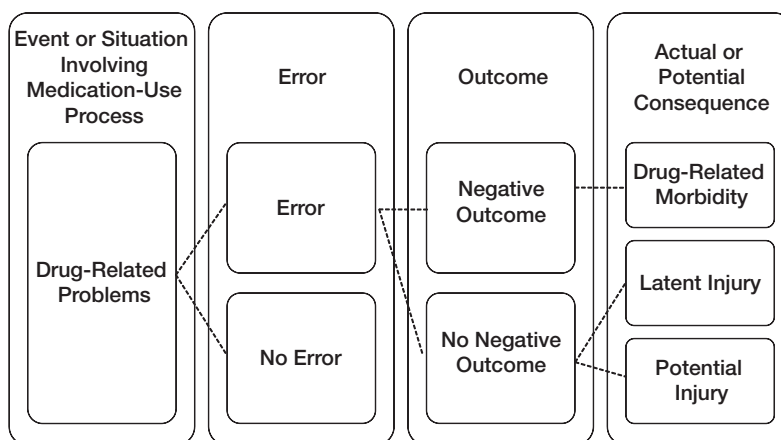


FIGURE 6-4. Various drug-related problems associated with errors.

Errors that lead to DRPs typically result because of something that an individual did (i.e., an *error of commission*) or did not do (i.e., an *error of omission*) (**Figure 6-5**). **Errors of commission** can occur when the patient receives either a correct drug or an incorrect drug. DRPs associated with receiving the correct drug occur when the patient receives too little or too much drug, when the patient reacts adversely to the drug, or when the correct drug interacts with foods, laboratory tests, or other drugs. DRPs associated with receiving the incorrect drug occur when the patient receives the wrong drug for that patient's condition or the patient receives a drug for which there is no medically valid reason. **Errors of omission** result in the patient failing to receive drugs that can be beneficial. DRPs associated with receiving no drug occur when the patient has a treatable condition that is left untreated or when a drug is prescribed but not taken.

PREVENTING MEDICATION ERRORS

Medication errors occur for a number of reasons. Some common reasons include look-alike and sound-alike drugs; sloppy communication practices including illegible handwriting, incorrect transcription, and verbal miscommunications; distractions and overwork; poorly designed medication labels; poor personnel management practices including inadequate performance feedback; the lack of a quality improvement system; and equipment failures.¹³

The IOM made a series of general recommendations relating to the prevention of medication errors¹⁴:

- Involve the patient in the medication-use process. This includes formalizing the rights of patients, educating them, and consulting with them.
- Consumer-oriented medication resources should be made available to support patient self-management of their medication use.
- Healthcare providers should have access to patient information and decision-support tools and technologies to enable them to be more active in monitoring and intervening.
- Medication labeling needs to be improved along with methods for communicating medication information to consumers.
- Health information technology must be improved to support the medication-use process.

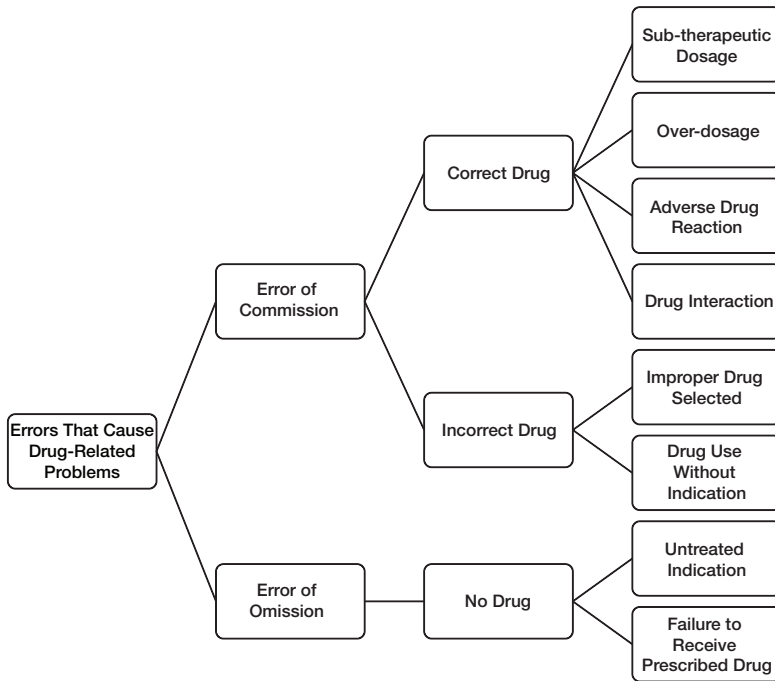


FIGURE 6-5. Types of medication errors.

- Congressional funding should be increased to study safe and appropriate medication use and error prevention.
- Healthcare payers and oversight organizations should be more active in promoting good medication-use practices.

Recommendations specific to pharmacies and pharmacists suggest a more active role in ensuring safe medication use.¹⁵ None of these recommendations is surprising except in the fact that they still are not being followed consistently in many pharmacy settings.

- Pharmacists must keep up with the medication literature for drug error information and take action for prevention.
- Pharmacists should verify the accuracy of new prescription data, monitor for errors and near misses, make corrections as needed, and report errors to external reporting programs.
- Patient identities should be verified using bar codes.
- Patients should be educated about ways to prevent medication errors.
- Patients should be engaged in managing their own medication regimens.
- Electronic prescribing should be used.
- Trivial warnings to prescribers and pharmacists should be avoided in medication decision-support systems.
- Prescription filling technology needs to be assessed and improved.
- Pharmacists should monitor patients for high-risk side effects.
- Pharmacists should routinely review patient medication records, especially when transitioning between types of care (e.g., hospital to community).

CULTURE OF SAFETY

One major reason medication safety problems have remained persistent in healthcare is providers and professionals do not have a culture of safety. Clearly, no one wants errors to happen and professionals make efforts to avoid errors, but a culture of safety is more than just having people who make efforts to avoid medical errors. A culture of safety exists where safety is a key element of everyone's job—from the leadership to the technicians and unit secretaries. In a culture of safety, leaders encourage workers to seek out and implement new ways of ensuring the safety of patients. This is done through actions (e.g., developing systems that promote safety) and words (e.g., asking people what the leader can do to help them ensure patient safety). In a culture of safety, people are obligated to take responsibility for protecting the well-being of patients. Inaction is frowned on by everyone—pressure to solve medication problems comes from technicians, pharmacists, and supervisors. Information is shared in a culture of safety because reducing patient risk is more important than concerns about disclosure.

However, sharing information about patient safety is easier said than done. In many pharmacies, the reporting of medication errors is discouraged by attempts to find someone to blame and punish for the error. In a culture of blame, adverse events and errors are rarely identified because the risk of reprisal discourages anyone from reporting them. Ignorance about the existence of medication errors means that they will continue to occur. A culture of safety tries to avoid blaming individuals, and instead focuses on identifying errors in the system that lead to errors. Thus, ensuring patient safety requires a change in the culture of work, medicine, medication-use systems, and human interactions.

KEY POINT . . .

A culture of safety exists where safety is a key element of everyone's job—from the leadership to the technicians and unit secretaries.

. . . SO WHAT?

The steps in a safe medication-use system are like the links of a chain. The system is only as good as the weakest link in the chain. Any individual involved in the medication-use process can influence patient safety for the good or bad—from the housekeeper to the chief executive officer. A culture is needed to promote the importance of everyone in ensuring patient safety.

MODELS OF QUALITY IMPROVEMENT

Organizations that seek to improve medication safety apply common models of quality improvement. A variety of models are available such as total quality management, continuous quality improvement, Six-Sigma, LEAN, or others. All models share the following principles:

- **The status quo is unacceptable** — According to the IOM and almost every other healthcare leader, the status quo harms patients and wastes money.¹ Therefore, change must occur, and it must be continuous. What was acceptable yesterday is no longer acceptable today. What is satisfactory now may be intolerable tomorrow.
- **Safety can be enhanced by improving the core processes of the medication-use system** — This means that safety will increase by identifying essential elements of the medication-use process and improving the process by eliminating duplication, avoiding unnecessary steps, decreasing process time, reducing errors, and simplifying the overall process.

- **Safety efforts must be patient-centered** — Unlike in the past, where practice revolved around the needs of the healthcare workers, the patient is now the emphasis. Solutions should then seek to serve the patient.
- **Quality must be measured** — Identifying problems with core processes requires establishing key measures of the process and monitoring them. For example, the quality of compounded intravenous (IV) solutions might be assessed by periodically culturing laminar flow hoods or systematically observing the process used by technicians in compounding. Unless quality is measured, it is not a priority, and there will be no way to identify whether it is improving, worsening, or staying the same.
- **Solutions to safety problems should address the system, not individuals** — Most DRPs are built into the system by design. Handwritten orders, use of abbreviations, transcribing orders by hand, paper-based charts, and numerous other quality deficiencies increase the likelihood that errors will occur and ADEs will take place. Attempts to blame single individuals or departments do not get at problems within the system. Indeed, errors in the system can strike anyone—pharmacist, technician, physician, or nurse—no matter how conscientious and competent. Poorly designed systems set up individuals to fail. Therefore, solutions to safety problems must address the overall system and cross organizational and professional lines.

KEY POINT ...

Unless quality is measured, it is not important.

... SO WHAT?

There is no way of telling if an institution provides high quality healthcare if it is not measured. Saying “We’re the best!” is a hollow boast without providing evidence to back it up. Quality must be measured because individuals can be held accountable for things that are measurable (e.g., number of consultations provided, frequency of reported errors). In addition, quality measures can be used in performance evaluations and affect compensation. Unless quality is measured, there is no accountability.

PDSA Cycle of Safety Improvement

A well-recognized process for improving the safety of medication-use systems consists of four steps—**Plan**, **Do**, **Study**, and **Act**—called the PDSA cycle (**Figure 6-6**). The PDSA cycle starts by first asking the following questions:

1. What do we want to accomplish?
2. How will we know when we are successful?
3. What changes will result in success?

Then the following steps are conducted:

- **PLAN** — This step attempts to clarify the purpose of the quality improvement effort. In this step, a bottom-up approach is typically preferred where everyone potentially involved in the process is consulted and engaged in the change—especially frontline healthcare workers. This is because frontline workers are more likely to understand the problems and ways to fix them. Within the medication-use system, technicians, pharmacists, nurses, unit secretaries, managers, and physicians might be consulted. Based on that input, a clear description of the problem is developed. An example problem statement might be, “The average time from

prescription to patient receiving a medication is 4 hours. This delay in therapy results in unnecessary longer lengths of stay for patients.”

The next part of the plan stage is to clarify the expected actions. Details need to be made clear including what actions will be taken, when and where, who will do them, and the specific responsibilities of those involved. This process can be made clear by mapping out the medication-use process with flow charts, root cause analyses, failure mode effects analyses, or other tools. For details about the many tools used in improving medication use, visit the ASHP and Institute for Healthcare Improvement (IHI) websites.

- **DO** — Once a plan has been established, it needs to be implemented. Implementation is typically done on a small scale to allow adjustments to the plan as experience with the problem is gained. Questions of interest include the degree to which the plan is implemented as designed and anything unexpected that occurs during the implementation.
- **STUDY** — This step (also called “CHECK” by some) studies the effect of the change on the safety measure. Collected data are analyzed to determine if the change has been successful and if any unintentional consequences (good or bad) have resulted due to the change. Questions of interest during this stage are the degree to which the desired results are achieved, what new knowledge is gained, and what adjustments might need to be made to improve the results.
- **ACT** — In this step, the small scale change is implemented on a larger level, and the entire process of monitoring and assessment starts over again. Changes from the small scale study might be warranted requiring further PDSA cycles. The key is that once a desired safety goal is achieved, a new goal is established that further improves the safety of patients within the medication-use process. The status quo is never acceptable, and change is continuous.

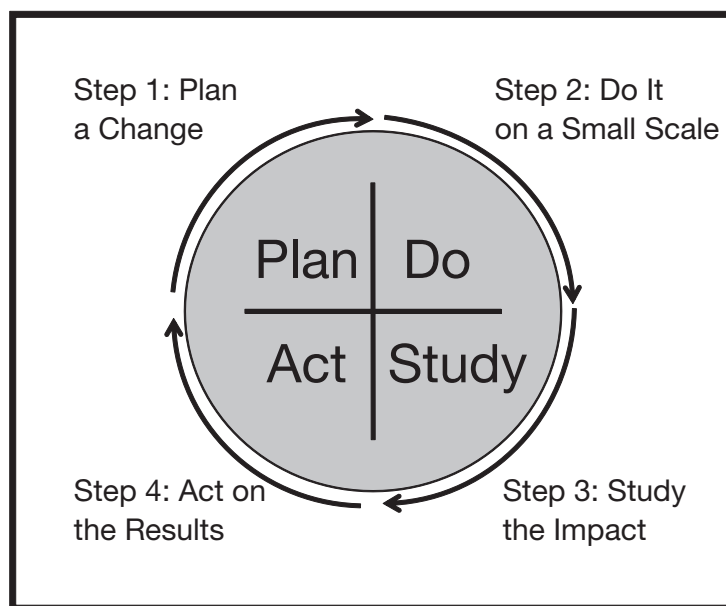


FIGURE 6-6. Plan-Do-Study-Act (PDSA) cycle of quality improvement.

Lean Management Processes

Another common quality improvement process for improving the safety of medication-use systems is the use of Lean Management processes. Lean is a set of philosophies and methods that empowers frontline staff such as pharmacists and technicians to challenge and change any activity or practice that consumes resources without adding value.¹⁶ Individuals use simple analytic tools to reducing waste, bottlenecks, and unnecessary waits in healthcare. It continually asks “What is the value provided in each step of the provision of healthcare?” Anything that does not add value is changed or deleted. Common wastes in healthcare that Lean Management attempts to reduce include¹⁷:

- Defects in products or service delivery
- Poor use of inventory
- Avoidable waiting
- Unplanned breaks in processes
- Unnecessary motion and steps in processes
- Duplication of effort
- Overproduction of services and products
- Underutilized employees
- Poor communication
- Inefficient transportation processes

In pharmacy practice, it has been used to reduce wasted continuous renal replacement therapy solutions in an academic medical center,¹⁸ improve time management of clinical pharmacists in a hospital,¹⁹ increase efficiency of oncology pharmacists,²⁰ and improve medication use in nursing homes.²¹

Measures of Health Care Quality

Healthcare quality can be measured in many ways. One of the frameworks most widely used is one suggested by Donabedian—Structure, Process, and Outcome.²² Donabedian stated that quality measures can be divided into the following three categories:

- **Structures** — These are measures of the presence of something that is reasonably associated with quality. One might expect the presence of a pharmacist and electronic medical records to be associated with safer use of medications. Structures are desirable for assessing the quality of healthcare because they are easy to measure—the number of pharmacists can be counted and the presence or absence of electronic medical records can be easily established. **Table 6-1** provides a list of structures associated with patient medication safety. The problem with structures is that their relationship with quality and patient safety is not always clear or established. Just because a pharmacist is there, for instance, does not mean that the pharmacist is doing the right things to ensure patient safety.
- **Processes** — These are actions reasonably associated with quality such as the checking of patient medication profiles prior to dispensing, double checking technician work, and electronic prescribing. **Table 6-2** provides a list of processes associated with patient medication safety. Although assessing the quality of processes is better than simply measuring the presence of structures, it is still possible that widely accepted practices are not always associated with positive patient health consequences. For example, many common preventive healthcare practices such as annual breast cancer screenings for women do not necessarily lead to positive patient health outcomes.

TABLE 6-1.
Structures That Should Be Present for Ensuring Safe Medication Use

STRUCTURES

- A *formulary system*, governed by a multidisciplinary pharmacy and therapeutics committee (or its equivalent) should have responsibility for formulating policies regarding the evaluation, selection, and therapeutic use of drugs.
- Effective *human resources* management must be present to effectively hire, manage, and train personnel involved in medication ordering, preparation, dispensing, administration, and patient education.
- *Adequate staffing* must be available to perform tasks effectively and ensure reasonable employee workloads and working hours.
- *Suitable work environments* should exist that minimize interruptions and distractions that might cause errors.
- *Lines of authority* and *areas of responsibility* within the medication-use process should be clearly defined for all individuals involved.
- An ongoing, systematic program of *quality improvement* and *peer review* relating to the safe use of medications should be present.
- *Clinical information about patients* (e.g., medications, allergies, and hypersensitivity profiles; diagnoses; pregnancy status; laboratory values) needs to be available to pharmacists and others responsible for processing drug orders.
- *Patient medication profiles* should be maintained for all patients. Profiles should include information that allows monitoring of medication histories, allergies, diagnoses, potential drug interactions and ADRs, duplicate drug therapies, pertinent laboratory data, and other information.
- *The pharmacy department must be responsible* for the procurement, distribution, and control of all drugs used within the organization.
- *Computerized pharmacy systems* should be in place to automate the drug-use process and provide better management of information.
- *Unit dose systems* are strongly recommended as the preferred method of drug distribution.
- Pharmacists should have access to *electronic health records*.
- *Computerized prescriber order entry* is the preferred method for prescribing medication orders.
- *Medication references* should be available to all healthcare providers.
- *Standard drug administration times* should be established to ensure consistency in the scheduled times patients receive drugs.
- *Standard abbreviations* should be established for medication ordering.
- A *review mechanism* must be in place to conduct retrospective reviews of drug-related problems.
- *Educational programs* should be in place to discuss medication errors, causes, and methods to prevent their occurrence.

Source: Adapted from reference 13.

- **Outcome** — Ultimately, the quality of safety systems needs to be assessed by their impact on patient health outcomes—dissatisfaction, discomfort, disability, disease, and death. Achieving positive health outcomes is the real purpose of having quality structures and processes. At the same time, they are the hardest to link to safety efforts. Thus, Donabedian suggested that a mix of structure, process, and outcome measures be collected to gain a true understanding of the quality of healthcare.²²

TABLE 6-2.**Processes Associated with Safe Medication Use****PROCESSES**

- *All drugs should be dispensed from the pharmacy department except in emergency situations.*
- *Storage of nonemergency floor stock medications on the nursing units or in patient care areas should be minimized.*
- *Routine inspections should be conducted of all drug storage areas.*
- *Use of a patient's own or "home" medications should be discouraged.*
- *All discontinued or unused drugs should be returned to the pharmacy immediately after discontinuation or at patient discharge.*
- *Discharge counseling of patients about their medication should be conducted.*
- *When in doubt, pharmacists should clarify any prescription.*
- *Manual transcription of physician orders should be minimized.*
- *Pharmacists should collaborate with the prescriber in developing, implementing, and monitoring a therapeutic plan to produce defined therapeutic outcomes for the patient.*
- *Pharmacists should participate in drug therapy monitoring such as assessing therapeutic appropriateness, possible duplication, potential interactions, and clinical data.*
- *Pharmacists should make themselves available to prescribers and nurses to offer information and advice about therapeutic drug regimens and the correct use of medications.*
- *Use of technology and support personnel in the medication-use process should be encouraged.*
- *Checks should be conducted on all work performed by support personnel or automated devices.*
- *For high-risk drug products, additional checks should be conducted when possible.*
- *Ready-to-administer medication dosage forms should be used whenever possible.*
- *Manipulation of drugs by nurses (e.g., measure, repackage, calculate) prior to administration should be minimized.*
- *Timely delivery of medications to nursing units should occur.*
- *Monitoring of actual administration should be conducted periodically to ensure safe administration by nurses.*
- *Pharmacists should collaborate with nurses to ensure safe administration of medications.*
- *Medications returned to the pharmacy should be reviewed for potential system breakdowns or medication errors (e.g., omitted doses, unauthorized drugs).*

MONITORING, REPORTING, AND COMMUNICATING**ADR Monitoring and Reporting Programs**

All institutions should have a comprehensive ADR monitoring and reporting program.¹² Any surveillance program should be conducted both concurrently and prospectively. One form of concurrent (during drug therapy) surveillance system is based on pharmacists', physicians', nurses', or patients' reports of suspected ADRs. Another form of concurrent surveillance monitors for alerting orders. Alerting orders are prescriptions that alert pharmacists an ADR may have occurred and an investigation needs to be conducted.¹² Several types of alerting orders occur. One is for *tracer* drugs commonly used to treat ADRs (e.g., orders for immediate doses of antihistamines, epinephrine, corticosteroids). When tracer drugs are used, an ADR may have occurred. Another form of an alerting order is any abrupt discontinuation or decrease in dosage of a drug—the assumption being that the discontinuation occurred because of a negative reaction to the medication. The last type of alerting

order concerns stat orders for laboratory assessments of therapeutic drug levels. This type of order alerts the pharmacist that some concern exists in the mind of the prescriber that too much or too little drug is in the patient's system.

One type of prospective (before drug therapy) surveillance system focuses on monitoring high-risk drugs or patients with a high risk for ADRs.¹² High-risk drugs include the following²³:

- Adrenergic agonists (IV) (e.g., epinephrine)
- Adrenergic antagonists (IV) (e.g., propranolol, metoprolol)
- Anesthetics (e.g., ketamine)
- Antithrombotics (e.g., warfarin, low molecular weight heparin)
- Cardioplegic solutions
- Chemotherapeutic agents
- Hypertonic dextrose
- Dialysis solutions
- Epidural and intrathecal medications
- Hypoglycemic agents (P.O.)
- Inotropic agents (e.g., digoxin, milrinone)
- Insulin
- Methotrexate (for non-oncologic use)
- Sedatives (e.g., midazolam)
- Narcotics/opiates
- Neuromuscular blocking agents (e.g., succinylcholine)
- Nitroprusside
- Oxytocin (IV)
- Potassium chloride and sodium chloride for injection
- Promethazine (IV)
- Radiocontrast agents
- Total parenteral nutrition

Populations at greatest risk for ADRs are those with the most trouble adjusting to the negative consequences.²⁴ Pediatric patients are at greater risk because drug responses are less predictable than with adults due to pharmacokinetic variations. This problem is aggravated because of the lack of clinical trials conducted in pediatric populations. On the other end of the age spectrum, the elderly are at greater risk due to issues of polypharmacy, multiple prescribers, adherence problems (due to memory or vision problems), changes in renal function and metabolism, and greater sensitivity to medications. Oncology patients commonly suffer ADRs because they are exposed to highly toxic therapeutic regimens and often are immunocompromised. Therefore, greater attention should be given to surveillance programs in these populations.

KEY POINT . . .

Alerting orders warn pharmacists that a potential ADR has occurred and an investigation needs to be conducted.

. . . SO WHAT?

Alerting orders are identified by understanding the best medical evidence and using the experience of pharmacists and other healthcare professionals. Alerting orders are based on the Pareto Principle—that 80% of all drug-related problems are associated with 20% of the orders. Knowing which orders are associated with the most problems allows pharmacists to give them more attention and develop specific strategies to deal with them (e.g., provide computer-generated warnings).

Several actions should occur when ADRs are suspected.¹² First, prescribers, nurses, and pharmacists should be notified. Notification should also be made to the pharmacy surveillance program for recording and analysis. Attempts should be made to determine the cause(s) of each suspected ADR using the patient's medical and medication history, the circumstances of the adverse event, and what might be found in any literature review. Ideally, a systematic method for assigning the probability of the reported or suspected ADR (e.g., confirmed or definite, likely, possible, unlikely) should be used to categorize each ADR. Serious or unexpected ADRs should be reported to the U.S. Food and Drug Administration (FDA) or the drug's manufacturer (or both).

Medication Reconciliation

In healthcare systems, confusion can occur about patient medication regimens as they transition throughout the system. Medication reconciliation is promoted as a solution. **Medication reconciliation** is the process of resolving discrepancies with what a patient has been taking in the past with what the patient should be taking at the moment. Medication reconciliation is an opportunity for pharmacists to use their knowledge and skills to enhance patient safety by identifying and resolving drug-related problems as patients transition throughout the healthcare system.

Reconciliation attempts to correct problems such as omissions in therapy, medication duplications, errors in dosing, and potential drug interactions. Medication reconciliation is meant to be conducted each time a patient transitions across departments (e.g., a medical ICU to a step down unit), locations (e.g., inpatient to outpatient), or other location. The medication reconciliation process consists of the following steps²⁵:

1. **Verification** — The most up-to-date list of medications currently being taken by the patient within the hospital or other institution is developed by using one or more sources of information—pharmacy profile, medical records, patient or caregiver interview, and patient medications brought to the institution.
2. **Clarification** — The medication and dosages are checked for appropriateness.
3. **Reconciliation** — Clinical decisions are then made based on a comparison of newly prescribed medications against what was prescribed previously. This might include discontinuing unnecessary medications and reordering medications placed on hold or temporarily discontinued. Changes to pharmacotherapy are documented in all relevant records.
4. **Transmission** — Therapy changes are communicated to people who need to know about the changes including providers on both ends of the transition (e.g., hospital pharmacist, community pharmacist, surgeon, internist), caregivers, and the patient. This step typically includes providing the patient or caregiver with a copy of the final medication list with administration instructions.

KEY POINT ...

Medication reconciliation requires pharmacists to take responsibility for patient medication safety as they transition to different parts of the healthcare system.

... SO WHAT?

In the past, what happened to patients after they left a pharmacy or institution was not a major role for pharmacists.

Accreditation organizations have now started to require institutions to conduct medication reconciliation. This is a key opportunity for pharmacists.

NATIONAL QUALITY ORGANIZATIONS

Numerous national organizations exist to promote healthcare quality and patient safety. The following are key organizations²⁶:

- **The Institute of Medicine (IOM)** — The IOM is a component of the National Academy of Sciences. Its mission is to “serve as adviser to the nation to improve health.” It has published a series of reports focusing on assessing and improving the nation’s quality of care including *Crossing the Quality Chasm*, *To Err Is Human*, and *Preventing Medication Errors*.
- **Institute for Healthcare Improvement (IHI)** — IHI is a not-for-profit organization with a goal of improving healthcare throughout the world. One major initiative of IHI was its 100,000 Lives Campaign that had a purpose of introducing proven best practices to extend or save as many as 100,000 lives. Its 5 Million Lives Campaign seeks to “prevent 5 million incidents of medical incidents over a two year period.”
- **National Quality Forum (NQF)** — The NQF’s primary role is in improving healthcare quality measurement and reporting. It endorses consensus-based national standards for measurement and public reporting of healthcare performance data that provide meaningful information about whether care is safe, timely, beneficial, patient-centered, equitable, and efficient. It has endorsed more than 300 measures, indicators, events, practices, and other products to help assess quality.
- **The Leapfrog Group** — The Leapfrog Group is a voluntary program of employers who use employer purchasing power to encourage the health industry to make big leaps in healthcare safety, quality, and customer value. It conducts the Hospital Quality and Safety Survey, which asks hospitals to rate themselves on four “leaps” of quality and safety practices. It also conducts the Hospital Rewards Program that measures performance in five areas for effectiveness and affordability and rewards excellent hospitals.
- **The Joint Commission** — Joint Commission assesses and accredits the quality of health systems. See Chapter Three: Key Legal and Regulatory Issues in Health-System Pharmacy Practice for more information about The Joint Commission.
- **Centers for Medicare & Medicaid Services (CMS)** — CMS manages Medicare and Medicaid programs, which contracts with a private Quality Improvement Organization (QIO) in each state to monitor care to Medicare beneficiaries. It sets quality standards that must be met to be able to serve CMS patients.
- **Agency for Healthcare Research and Quality (AHRQ)** — AHRQ conducts and supports research for the U.S. Department of Health and Human Services (HHS) in the areas of quality improvement and patient safety, outcomes and effectiveness of care, clinical practice and technology assessment, and healthcare organization and delivery systems. It sponsors the National Quality Measures Clearinghouse (NQMC), a public repository for evidence-based quality measures and measure sets.
- **National Committee for Quality Assurance (NCQA)** — NCQA manages the Health Plan Employer Data and Information Set (HEDIS), which provides purchasers and consumers with information about the quality of healthcare plans.
- **ASHP** — ASHP supports health-system pharmacists in quality and safety through publishing (e.g., books, *American Journal of Health-System Pharmacy*), education (e.g., professional meetings, continuing education, ASHP website), advocacy, and guidance documents (e.g., ASHP guidelines on adverse drug reaction monitoring and reporting).

- **Pharmacy Quality Alliance (PQA)** — PQA is a consortium of pharmacy organizations that brings key stakeholders together to agree on strategies for measuring performance at the pharmacy and pharmacist-levels; collecting data in the least burdensome way; and reporting meaningful information to consumers, pharmacists, employers, health insurance plans, and other healthcare decision-makers to help make informed choices, improve outcomes, and stimulate the development of new payment models.



SUMMARY

Medication safety is a fundamental responsibility of all pharmacists who work in institutional practice, and it is part of their core mission. The complexity of the medication-use process requires pharmacists to have knowledge about types of safety problems, the causes of errors and drug-related morbidity, and practices that can reduce them. The connections between various components of the medication-use process require pharmacists to take responsibility for the entire process—not only what goes on in the pharmacy. The problems of medication safety are complex; therefore, quick fixes and simplistic solutions will not resolve them. Commonly recommended solutions like the use of technologies such as bar-code monitoring, computerized prescriber order entry systems, and electronic medical records are not panaceas. They are only part of the solution. Other parts may incorporate training, improved workflow, and good leadership.

SUGGESTED READING

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CHAPTER REVIEW QUESTIONS

1. **Drug-related problems include medication errors, adverse drug reactions, medication side effects, and adverse drug events.**
 - a. True
 - b. False

Answer: a. True. They are all drug-related problems because they are events associated with drug therapies that can or do hamper optimal patient health outcomes.

2. **Which of the following is never caused by a medication error?**
 - a. Side effect
 - b. Adverse drug event
 - c. Adverse drug reaction
 - d. Allergic reaction

Answer: a. Medication errors are errors or mistakes in the medication process (prescribing, dispensing, administering of drugs) that may result in negative outcomes. Side effects are well-known reactions that are expected and not due to error. Adverse drug reactions and adverse drug events are unexpected, undesired, and often result from error. Allergic reactions are types of adverse drug reactions that can be caused by errors.

3. **Which of the following sometimes directly results in drug-related morbidity?**
 - a. A latent injury
 - b. A potential injury
 - c. An adverse drug event
 - d. An allergic reaction
 - e. An adverse drug reaction

Answers: c, d, and e. Negative health outcomes associated with medical errors are called drug-related morbidity. Latent injuries and potential injuries do not actually result in patient injury—they are only a propensity or predisposition for harm. Adverse drug events

and adverse drug reactions such as an allergic reaction may result in harm and may be due to error.

4. Pharmacists in health-system practice are responsible for errors in dispensing.

- a. True
- b. False

Answer: a or b depending on how the question is interpreted. If the statement is interpreted as “only responsible for errors in dispensing,” then the answer is false, because pharmacists are responsible for all parts of the drug-use process including prescribing, administration, and monitoring. If the question is interpreted as this being one responsibility in the drug-use process, then the answer is true.

5. Latent injuries are not important because they do not result in actual injury.

- a. True
- b. False

Answer: b. False. Latent injuries indicate problems in the medication-use process. They may not result in injury, but they do warn pharmacists of issues that might eventually hurt patients.

6. Which of the following is NOT an important principle of quality improvement?

- a. The status quo is unacceptable.
- b. People are the reason for poor patient safety.
- c. Safety can be enhanced by improving the core processes of the medication-use system.
- d. Safety efforts must be patient-centered.
- e. Quality must be measured.

Answer: b. People may make errors and do less than they are capable of doing in health-care, but quality improvement works under the assumption that the system is the problem. Individuals make mistakes because of flaws in the system whether those flaws are due to poor human resources management, work flow problems, lack of necessary tools and technology, etc.

7. In which step of the PDSA cycle is a quality problem statement developed?

- a. Plan
- b. Do
- c. Study
- d. Act

Answer: a. In this stage, the problem is defined and a plan is developed. The plan is implemented on a small scale in the Do stage. The results are assessed in the Study stage. Finally, the plan is implemented on a larger scale in the Act stage based on lessons learned in the other stages.

8. The best indicator of healthcare quality is positive patient health outcomes.

- a. True
- b. False

Answer: a. True. Ultimately, healthcare seeks positive patient health outcomes. Structures (e.g., a clinical pharmacist) and processes (e.g., providing clinical therapy) are means to achieving an end—positive health outcomes. However, an argument can be made that the answer is false because the best indication of quality really depends on the circumstances.

Depending on the situation, structures, processes, or outcomes could be superior indicators.

9. Which of the following is classified as a STRUCTURE according to Donabedian?

- a. Health-related quality of life
- b. Medication reconciliation
- c. A unit dose system
- d. Mortality
- e. Collaborating with nurses

Answer: c. A unit dose system is classified as a structure because its presence is associated with quality healthcare. Health-related quality of life and mortality are outcomes of healthcare. Medication reconciliation and collaborating with nurses are processes.

10. Which of the following organizations conducts and supports research for HHS in the areas of quality improvement and patient safety, outcomes and effectiveness of care, clinical practice and technology assessment, and healthcare organization and delivery systems?

- a. Leapfrog group
- b. IHI
- c. NQF
- d. NCQA
- e. AHRQ

Answer: e. Agency for Healthcare Research and Quality is the health services research arm of HHS. IHI is a not-for-profit organization that promotes healthcare quality improvement, including its 100,000 Lives Campaign. The NQF endorses consensus-based national standards for measurement and public reporting of healthcare performance data. The Leapfrog Group is a voluntary program of employers who seek to recognize and reward excellent healthcare organizations. NCQA manages HEDIS, which is used to provide purchasers and consumers with the information about the quality of healthcare plans.

CHAPTER DISCUSSION QUESTIONS

1. Which types of errors are easier to detect—errors of omission or errors of commission?
2. What features might you expect to see in a pharmacy that has a culture of safety?
3. What is a pharmacist's responsibility within the medication-use system? What is not the pharmacist's responsibility?
4. What do you think are the biggest barriers to a safe medication-use process?
5. What do you think are the biggest barriers to pharmacist involvement in the medication-use process (other than time)?

Medication Distribution Systems

Stephen F. Eckel, Jami E. Mann, and Fred M. Eckel

LEARNING OBJECTIVES

After completing this chapter, readers should be able to:

1. Describe the advantages and disadvantages of floor stock, patient prescription, and unit dose medication distribution systems.
2. Contrast the advantages and disadvantages of centralized and decentralized models of distribution.
3. Discuss the evolution of medication distribution over the past few decades and its impact on the professional role of pharmacists.
4. Identify technologies used in managing medication distribution.
5. List the attributes of a good medication distribution system.
6. Define key terminology associated with medication distribution systems.

KEY TERMS AND DEFINITIONS

- **Automated dispensing cabinets (ADCs):** Point-of-use medication storage devices located in patient care areas, which are designed to allow nurses quick but accountable access to medications. Most systems have some form of user identifier or password that restricts access to the medications.
- **Centralized pharmacy services:** A model that distributes medications from a centralized pharmacy location.
- **Decentralized pharmacy services:** A model that distributes medications from multiple ADCs located on the nursing unit. Some models might utilize a decentralized satellite pharmacy, but this is not as common today.
- **Floor stock system:** A system of distribution that consists of an individual storage area on each nursing unit where drugs are stored prior to preparation and administration by the nurse. The medications are usually unsecured in this system, and the role of pharmacy is primarily distributional.
- **Medication administration record (MAR):** A record of all current medications prescribed for each patient. The records contain information on the drugs, administration times, and directions for use. Nurses use MARs to know what medication each patient should receive at what time and how. MARs are also used to document that the drug was given by whom and at what time. Although this was historically documented on paper, most hospitals now utilize electronic MARs.
- **Medication profile:** The primary record that pharmacists use to document patient medications.
- **Patient prescription system:** An antiquated system of medication distribution that consists of patient-specific containers with a 2- to 5-day supply of drugs delivered to and stored on nursing units. Within this system, drug orders are transcribed by the nurse and reviewed by a pharmacist although no patient information is available to the pharmacist.

- **Unit dose system:** A system of distribution coordinated by the pharmacy that dispenses medication orders to be administered, not prepared, by the nurse. This system is characterized by medications contained in unit dose packages and dispensed in ready-to-administer form with no more than a 24-hour supply being delivered or available on the patient care unit at any time. Pharmacists monitor and coordinate unit dose systems by reviewing all medication prescriptions against patient medication profiles and managing the distribution and storage process.
- **Unit-of-use package:** A container with the exact dose needed for patients in a ready-to-administer form, not requiring any preparation or selection by the nurse upon documentation.



INTRODUCTION

The role of the pharmacist has always been to ensure that patients receive the appropriate medication in an acceptable dosage form that facilitates safe administration and improved outcomes. At different times in pharmacy's evolving responsibilities, some aspects of this role seemed to receive more attention. In the early days of institutional pharmacy, the pharmacist's role was distributional—developing systems of drug delivery that reduced waste and minimized medication errors. Pharmacists have become more and more involved in clinical responsibilities as time has progressed. Despite the expanding clinical role of pharmacists in inpatient and ambulatory settings, distribution of drug products will continue to be an important responsibility of pharmacists in healthcare institutions.

The unit dose system transformed the evolution of institutional pharmacy practice.¹ The system required pharmacists to receive individual patient medication orders, which changed their roles and enabled them to become members of the healthcare team. The pharmacist would review those orders against patient medication records prior to preparing and dispensing patient-specific doses in a ready-to-administer form. This allowed the hospital pharmacist to assume responsibility for a patient's drug therapy and established a platform for clinical pharmacy and pharmaceutical care to be successful. Over the past 50 years, there have been many improvements to the unit dose system, mostly through advancements in technology and the expanded clinical role of the pharmacist.

This chapter provides a brief overview of the history of the medication distribution system leading to unit dose, a discussion of the unit dose system, an analysis of different technologies that assist drug distribution today, and thoughts on the future of medication distribution.

HISTORY OF MEDICATION DISTRIBUTION SYSTEMS LEADING TO THE UNIT DOSE CONCEPT

The role of the hospital pharmacist 60 years ago was primarily confined to the basement.² The space was small, and the personnel involved in drug distribution were few. The pharmacist's primary role was to purchase and prepare medications to be used on the nursing unit. The physician would prescribe the medication, and the nurse would administer it to the patient. The pharmacist was rarely involved in assessing the appropriateness of therapy. He or she simply made sure that the nurse had a supply of medication for the patient. If repackaging or compounding of the medication was required, the pharmacist accepted responsibility for this function with the exception of intravenous (IV) admixtures, which nurses usually prepared on the nursing unit.

The pharmacist would utilize at least two distinct distribution methods for the nurse to obtain the medications for patient use.² The first was referred to as the floor stock system, and the second was the patient prescription system.

Floor Stock System

The **floor stock system** consisted of an individual storage area on each nursing unit where medications were kept prior to the nurse preparing them to administer to patients. The medications were largely unsecured. The pharmacist was responsible for stocking the nursing unit storage area. The pharmacist would place bulk containers of medications in the unit storage area, often called the drug room. There were multiple doses in each bottle to supply all patients receiving that drug on the nursing unit. The nurse was the professional responsible for preparing the patient-specific medications for both oral and IV use. The nurse would read the physician order, go into the drug room to select the drug and prepare it, and then administer it to the patient. In this selection process, the nurse could choose from many different medications. If a medication needed to be refilled or a patient was started on a different drug, the nurse would request the new medication to be stocked on the nursing unit. The pharmacist would likely never see the physician order and would stock the medication on the floor solely from the nursing request. This system was utilized because it required minimal pharmacy resources, and it was assumed that this distribution system was safe. Patients were charged only for the drugs administered to them or were billed a daily fee, also termed *per diem*, for the drugs.

KEY POINT . . .

In the floor stock system, the nurse was the professional responsible for preparing the patient-specific medications for both oral and IV use.

. . . SO WHAT?

Nurses receive only a fraction of the training pharmacists get in the preparation and handling of medications. In addition, nurses have numerous responsibilities that can force them to give medication preparation less attention than desirable. Distribution systems have evolved to allow pharmacists to take much of the burden of medication preparation from nurses.

Patient Prescription System

In contrast, the **patient prescription system** involved the pharmacist to a greater extent than the floor stock system by requiring a review of the patient order. After the physician wrote the order, the nurse would transcribe the medication order and send it to pharmacy for preparation. The pharmacist would prepare a 2- to 5-day supply of medications for the patient and charge the patient for the medications dispensed. The nurse would store the medication on the nursing unit. This system still required the nurse to prepare the individual dose for the patient. When the drug needed to be refilled, the nurse would contact the pharmacist who would prepare it and send it to the floor for continued use. When the drug was discontinued or the patient was discharged, the prescription containers were returned to the pharmacy and the unused drugs were credited to the patient's account. Even though the pharmacist had the opportunity to review the patient order, the pharmacist would place only limited judgment on whether it was correct or appropriate for the patient. This was because the pharmacist did not have access to pertinent patient information, and this activity was not expected of them.

UNIT DOSE SYSTEM

The move from floor stock and patient prescription systems to unit dose was driven by several studies that found the floor stock and individual prescription system to be error-prone.³⁻⁵ Based on these studies, a few hospitals began experimenting with the unit dose system which seemed to be safer and was believed to offer more opportunities for pharmacists to improve the medication-use process.^{4,6} This move to unit dose placed the pharmacist in a position to begin affecting a patient’s medication therapy.

The **unit dose system** is defined as a pharmacy-coordinated method of dispensing and controlling medications in healthcare institutions.⁷ This system is characterized by medications contained in unit dose packages, dispensed in ready-to-administer form, with not more than a 24-hour supply delivered or available on the patient care unit at any time. The pharmacist dispenses patient-specific medications to be administered, not prepared, by the nurse. **Figure 7-1** compares the unit dose process with features of floor stock and patient prescription systems.

In 1971, the U.S. General Accounting Office concluded that the unit dose system was the most cost-effective of any distribution system—especially when the entire medication-use process is considered.² Studies have shown the reduction of medication errors when transitioning from the floor stock system to the unit dose system to be 2% to 11% of all orders studied.³⁻⁵ Advantages of the unit dose system are listed in **Table 7-1**. Unit dose distribution has been adopted by almost all hospital pharmacies in the United States.^{8,9}

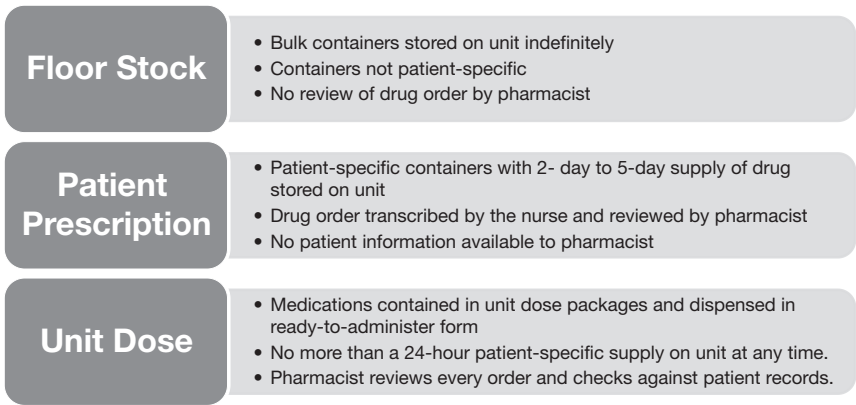


FIGURE 7-1. Comparing key features of medication distribution systems.
Source: Courtesy of David Holdford.

TABLE 7-1.

Advantages of the Unit Dose Distribution Method⁷

- Reduction in medication errors
- Decrease in total cost of medication-related activities
- More efficient use of pharmacy and nursing personnel
- Improved drug control and drug-use monitoring
- More accurate patient billing for medications
- Minimization of credits for drugs
- Greater control by pharmacist over work patterns and scheduling
- Reduction of inventories maintained on nursing units

Source: Originally published in ASHP statement on unit dose drug distribution. *Am J Hosp Pharm.* 1975; 32:835. ©1975, American Society of Health-System Pharmacists, Inc. All rights reserved. Used with permission.

ROLE OF UNIT DOSE ON DRUG-USE CONTROL

Implementation of unit dose systems in institutions had a critical role with involving pharmacists in the process of medication prescribing, distribution, and administration. Unit dose placed pharmacists front and center in the medication-use process. It required pharmacists to review every medication order prior to dispensing. Duplicate carbon copies of the original orders were provided to pharmacists to prevent transcription errors seen in systems that had nurses or unit secretaries hand copy the originals for pharmacists. Seeing prescription orders prior to dispensing let pharmacists intervene if needed prior to the first dose of any order made available to the patient. This important step provided a new role for pharmacists that made much better use of their knowledge and training.

Another important advance for pharmacists provided by the unit dose system was that it required the pharmacy to have and maintain a patient **medication profile**.¹⁰ This allowed pharmacists to gain access to patient-specific information, including the following¹⁰:

- Patient's name and location
- Generic name of medication
- Dosage in metric system, where feasible
- Frequency of administration
- Route of administration
- Signature of the physician
- Date and hour the order was written

This eventually led to the pharmacy department taking responsibility for the updating and printing of the **medication administration record (MAR)**.

The enhanced role of pharmacists helped propel clinical pharmacy services. Instead of being focused solely on getting the correct drug to the nursing unit (for nurse selection and administration), pharmacists also began evaluating whether the drugs sent were appropriate for the patient.

Efficient distribution systems are essential for developing the credibility to provide clinical pharmacy services. If pharmacists cannot ensure that they can provide reliable and responsive distribution of medications for patients, it will be difficult for them to convince physicians and nurses that pharmacists can be relied on to provide clinical services. Hence, clinical services can be built only on the foundation of excellent medication distribution systems.

The Unit Dose Process

The unit dose process is employed by almost all hospitals in the United States; however, the process varies with each institution.^{8,9}

Therefore, the following description of unit dose systems in this section may not be completely illustrative of that seen in many institutions. Nevertheless, this section provides a general description of key steps in the unit dose order fulfillment process (**Figure 7-2**).

KEY POINT . . .

An efficient and well-run distribution system lends essential credibility to the pharmacy department and facilitates the ability of pharmacists to provide more clinical services.

. . . SO WHAT?

A pharmacist's ability to influence others involved in the medication-use process is based in large part on the pharmacist's reputation. That reputation can be damaged by a poorly run distribution system, minimizing the opportunity to get involved in other major initiatives. Indeed, the best clinical pharmacy services can be undercut by a distribution system that is inept and wasteful.

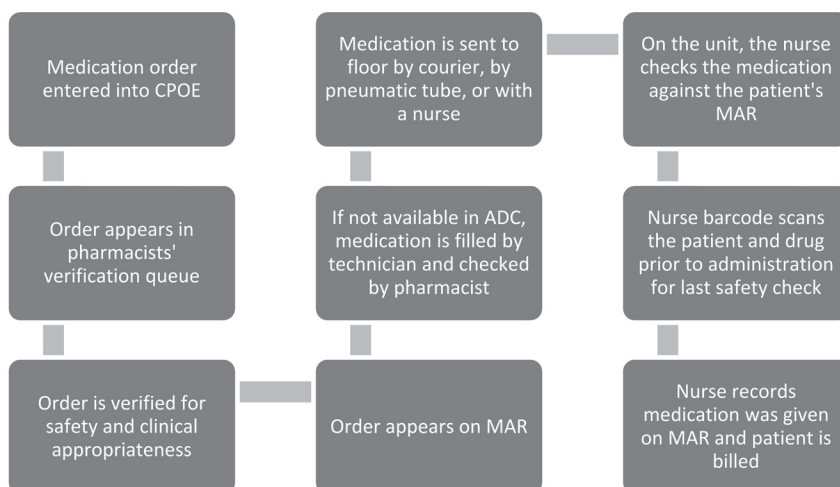


FIGURE 7-2. Unit dose order fulfillment process for a completely automated organization. The process will vary depending on the institution (e.g., many do not have pneumatic tube systems), level of technology in the system (e.g., use of automated dispensing cabinets), and type of medication (e.g., controlled medicines require different handling).

ADCs: automated dispensing cabinets; CPOE: computerized provider order entry; MAR: medication administration record

In the majority of hospitals today, various software vendors enable electronically written orders via computerized provider order entry (CPOE). After the prescriber electronically signs the orders, they are immediately available in an electronic queue that can be filtered based on unit or medical service or priority (stat versus routine). The pharmacist can electronically review the orders on a computer.

Prior to CPOE, and in a small percentage of hospitals today, orders are hand written and sent to the pharmacy through various methods. These handwritten orders are delivered by courier, pneumatic tube systems (i.e., pressurized tubes that move small containers throughout institutions), or facsimile devices.

Upon receipt of the medication order, the pharmacist reviews the order and pertinent patient information to ensure the medication is safe and appropriate for the patient. Due to electronic health records (EHRs), pharmacists and various other healthcare providers have access to the entire medical charts, which contain laboratory results, pharmacy orders, vital signs, progress notes, etc. After reviewing pertinent patient information, the pharmacist clarifies any discrepancies with the prescriber. When the order is appropriate, the medication is verified, or electronically approved, by the pharmacist. This verification makes the medication active on the electronic MAR.

After each physician order, the MAR is updated electronically. The MAR is a record of all the patient's prescribed medications, including administration times. **Figure 7-3** shows a copy of an electronic MAR. Prior to giving the new medication to the patient, the nurse double-checks the MAR against the patient order to ensure that it is appropriate. The majority of hospitals have bar-coded medication administration (BCMA) systems that allow for an automated check of patient identity, appropriate medication, and ordered dosage. Scanning at the bedside ensures patient safety, records the administration on the MAR, and potentially bills the patient for the medication.

In completely computerized record keeping systems, the MAR is updated instantaneously with each new order entered in the pharmacy medication profile. For some systems,

Monday January 25, 2016							
0400	0500	0600	0700	0800	0900	1000	1100
glimepiride (AMARYL) tablet 8 mg : Dose 8 mg : Oral : Daily ⓘ Rx							
			0730 Due				
insulin regular (HumuLIN, NovoLIN) injection 0-12 Units : Dose 0-12 Units : Subcutaneous : 3 times daily before meals : ⓘ Rx							
			0730 Due				1130 Due
morphine injection 1 mg : Dose 1 mg : Intravenous : Every 4 hours PRN : pain, severe (7-10) ⓘ Rx							
				0853 Given 1 mg			
oxyCODONE-acetaminophen (PERCOCET) 5-325 MG 1 tablet : Dose 1 tablet : Oral : Every 6 hours PRN : pain, moderate (4-6) ⓘ Rx							

FIGURE 7-3. Copy of a medication administration record (MAR). MARs vary according to the software system used.

Source: © 2016 Epic Systems Corporation. Used with permission.

specifically those without an integrated EHR with BCMA, a hard copy of each MAR is printed every 24 hours from the pharmacy's computerized patient profile. Any changes in the patient medications are updated manually on the nursing unit until the next computerized MAR is delivered.

One goal of unit dose systems is to reduce the cognitive burden on nurses in the administration process. One way of accomplishing this is the **unit-of-use package**.² Unit-of-use packages (also known as unit dose packages) contain the correct dose for the patient in a ready-to-administer form and do not require any preparation by the nurse. The medication will have a label that bears the name of the medication, the corresponding strength, expiration date, and bar code identifier. The nurse should be able to check the MAR, find the exact unit-of-use package in an individual patient's medication bin or automated dispensing machine, and give it to the patient with minimal effort beyond double-checking the MAR and directions for administration. The majority of drugs in institutions can be purchased from manufacturers in unit dose packaging. Medications from bulk bottles can also be repackaged into unit-of-use packages in the pharmacy.

Medication storage can occur via an **automated dispensing cabinet (ADC)** (discussed later in this chapter) or manual cart. Over the past 15 years, ADC utilization has increased from 49% to 97% in hospitals.⁹ ADCs contain storage areas for frequently used unit dose medications (e.g., solid dosage forms), including controlled substances. In addition, ADCs may have patient-specific bins housing unit-of-use medications that may come from the central pharmacy (e.g., IV medications requiring sterile preparation in a cleanroom or infrequently used medications stored in the inpatient pharmacy).

ADC inventory is managed electronically via minimum and maximum amounts. When an inventory level of a certain drug reaches the minimum threshold, a label will print in the pharmacy. The name of the ADC, medication name, quantity needed to return to the maximum inventory, and a bar code is communicated via the label. A pharmacy technician obtains the medication and labels it. The pharmacist then checks the medication, and the replenishment stock is delivered to the ADC. The technician logs into the ADC and scans the label's bar code. The ADC will direct the technician to the correct pocket to place the medication, which decreases the chances of incorrect stock.

The minority of hospitals utilize medication carts for storage on the patient care unit. Medication carts contain two separate sections. One is a common area of the cart where bulk medications and floor stock can be stored. The other section contains individual patient medication bins. Each patient bed has a separate compartment (i.e., bin) where an individual patient's unit-of-use medications are stored. The pharmacy fills these patient medication bins, which can only be accessed by a nurse or other appropriate representative. Carts have wheels but are usually kept stationary.

The medications in this cart are exchanged daily with new ones for that day. Unused medications are removed from the cart. The cart replenishment process starts again. The pharmacy technician fills the carts, and a pharmacist checks it before it is exchanged. If done properly, this cart replenishment can be completed in a short period of time.¹¹ In some states, technicians can substitute for pharmacists in double-checking the accuracy of filling the unit dose cart (i.e., non-patient-specific medications).

If the pharmacy receives a new patient medication order or a dose request from the nurse, the pharmacist provides the medication directly to the floor. Drugs can be delivered to the floor either through a courier or pneumatic tube system. The number of items sent for the new order will provide enough doses until the next cart fill delivery.

Although unit dose systems rely on cart delivery for many drugs, some medications have unique handling and delivery instructions. Therefore, unit dose systems exist alongside floor stock and other distribution systems. **Table 7-2** lists a sample of the different storage methods used for a typical patient care unit at a tertiary care hospital.

Narcotics, PRN (as needed) medications, and emergency drugs follow a different process than the classic unit dose system. Schedule II narcotics, because of Drug Enforcement Administration (DEA) requirements, cannot be stored in the individual patient bins in a medication cart because they do not provide sufficient security. Instead, in a non-automated environment, they are usually stored in a locked cabinet with access limited to a few individuals (e.g., nurse-in-charge). Prior to giving controlled medication doses, the nurse takes an inventory of the medication and documents the doses removed. Discrepancies are reported immediately. Nursing also takes an inventory at each shift change to reconcile the number of orders against the number of medications given to minimize the chance of diversion. Periodically, pharmacy personnel take inventory of the controlled medications on the nursing unit to verify records and ensure that no diversion has taken place. Although time intensive, this process effectively reduces diversion.^{12,13} Another more common option for managing controlled substances is an ADC.

PRN medications are handled according to different institution-specific methods. One method is to keep them in the pharmacy and dispense upon request. This system provides the most control over medication distribution, but it is rarely used because of the time burden on nurses and pharmacists and resulting delays in dispensing and administration. Another method is to send up a small amount of PRN medications for each patient in their patient-specific medication bin. If the patient requests a dose, the nurse retrieves the

KEY POINT . . .

One goal of unit dose systems is to reduce the cognitive burden on nurses in the administration process.

. . . SO WHAT?

Spend some time on the nursing unit and watch the numerous tasks nurses have to perform. Research studies in the social sciences have concluded that multitasking by anyone, including nurses, increases the chances for error due to inattention and distraction. Unit dose systems seek to reduce the cognitive burden and errors associated with multitasking.

TABLE 7-2.**Medication Delivery from Pharmacy to Patient Care Unit²**

Medication Category	Delivery/Storage Method
1. Stable scheduled medications	A 24-hr supply is kept in a patient-specific bin in the ADC on the unit
2. Unstable scheduled medications	Automatic delivery of medications to the unit 1 hr before administration time (usually by nursing request)
3. Scheduled IV/TPN solutions	Automatic delivery of medications to the unit before administration time (usually through batch processing)
4. PRN medications	A limited supply is kept in a patient-specific bin. Some frequently used PRN medications are kept in ADCs (e.g., acetaminophen)
5. Controlled medications	Supply is secured in an ADC
6. STAT medications	Delivered by the pharmacy in response to a request from the unit
7. Emergency medications	Emergency drug kits are located on units and replaced by the pharmacy in response to a request from the unit
8. Investigational medications	Per investigational drug protocol

ADC: automated dispensing cabinet; IV: intravenous; PRN: as needed; STAT: immediate use; TPN: total parenteral nutrition

Source: Reprinted with permission from Black HJ, Nelson SP. Medication distribution systems. In: Brown TR, ed. *Handbook of Institutional Pharmacy Practice*. 3rd ed. Bethesda, MD: ASHP; 1992:165-74.

medication from the medication cart. The downside to this process is that many doses are sent daily to the nursing unit and returned unused. This is inefficient because it adds time to the cart replenishment process and reduces inventory turnover.^{14,15} Most hospitals now utilize ADCs to provide quick access to frequently used PRN medications for nursing. This is usually referred to as *floor stock medications*. If the patient requests a dose, the nurse removes the medication from the ADC according to the parameters of the order, administers the dose, and records the administration on the MAR. Billing of the medication will take place, and the inventory is decremented appropriately.

Distribution of emergency medications is another area for pharmacy oversight. Emergency medications are a select number of drugs needed to be kept on-site to respond immediately to patients who deteriorate quickly due to failure of major organ systems. Emergency medications must be available instantly because any delay can be catastrophic for the patient. These medications are made available throughout the hospital in tamper-evident boxes or carts (sometimes called *crash carts* or *code carts* or *medication kits*). An example of a cart is shown in **Figure 7-4**. Carts typically contain non-drug items (e.g., defibrillator, medical supplies), IV solutions, and medications (e.g., epinephrine). Medications are in

KEY POINT . . .

In many institutions, pharmacists respond to medical codes and assist in the drug selection, preparation, and administration.

. . . SO WHAT?

The public perception of pharmacists is of an individual working in an out-of-the-way, calm, and quiet area. Many people would be surprised to see pharmacists responding to medical codes in nursing units and advising physicians and nurses on appropriate use of emergency medications.

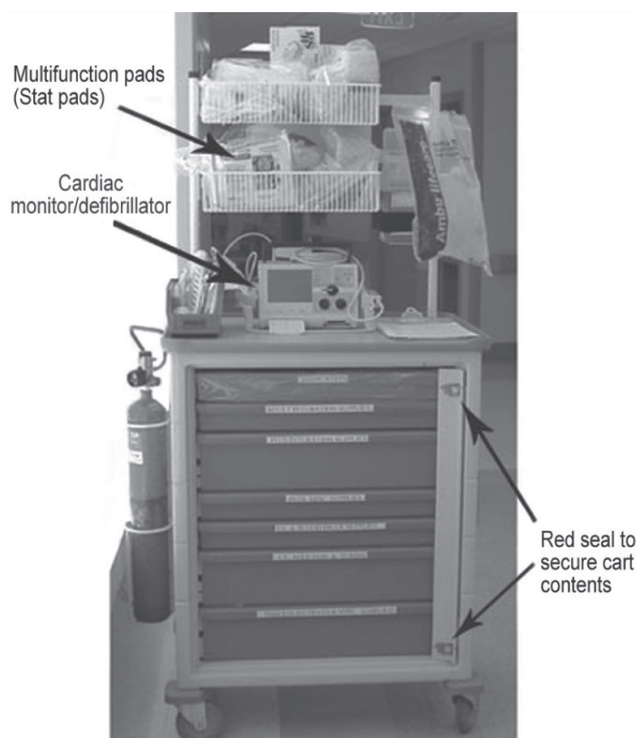


FIGURE 7-4. An emergency crash cart. Emergency medications are stored in the tamper-evident red drawers.

Source: Available at: http://www.ucdmc.ucdavis.edu/cne/resources/clinical_skills_refresher/crash_cart/

ready-to-administer form and located on nursing units or any other location an emergency may occur in an institution. Pharmacy personnel periodically check the carts to ensure that they have not been tampered with and to replace expired medications. In many institutions, pharmacists respond to medical codes and assist in the drug selection, preparation, and administration.^{16,17}

MODELS OF UNIT DOSE DELIVERY

There are two main models used to structure unit dose services: centralized and decentralized models. A **centralized model** emanates from the main pharmacy (a centralized location). Medication orders are received in the central pharmacy, and all of the processing for patients occurs there—order processing, drug packaging, cart fill, and medication dispensing. The advantages of this model are that all resources can be localized into one area and drug inventory can be minimized.

A **decentralized model** can be characterized by first doses and maintenance doses being delivered outside of the central pharmacy, which can be accomplished using ADCs. For first dose and maintenance doses, utilization of ADCs has grown from 49% of hospitals using ADCs in their distribution model to 97% in 2014.⁹ Advantages of medication storage via ADCs is faster turnaround time for first doses, automated controlled substances tracking, and increased nursing satisfaction. The disadvantages of an automated distribution system may include nurses preparing the final dose (e.g., drawing up a patient-specific dose from a single dose vial or splitting a tablet) and increased inventory carrying cost for the department. Additionally, inaccurate inventory and the potential for medication errors are possibilities when using matrix drawers in ADCs.¹⁸ Hospitals are increasingly relying on lidded pockets versus open matrix drawers as the primary configuration of their ADCs.⁹

Another characterization of a decentralized model is having pharmacy satellites located throughout the institution.¹⁹ A physician order is routed to a designated satellite where the pharmacist processes the order and dispenses the first dose of the medication directly to the nursing station. Because pharmacists are located near patient care areas, it is very easy for physicians and nurses to stop by to ask a question. The pharmacist can also go into the patient care areas to speak with a patient or provide clinical services. By having a satellite covering only certain patient care areas, the pharmacist can be more knowledgeable about specific disease states or unique prescribing patterns or habits of physicians. A centralized pharmacy still needs to support the pharmacy satellite as well as provide services to the hospital after the satellite closes. Pharmacy satellites can provide specialized services in pediatrics, oncology, critical care, the emergency department, and the operating room.²⁰⁻²⁴ The advantages with a decentralized model compared to a centralized model include faster order filling, increased physician and nursing satisfaction, better professional relationships between pharmacy and other departments, expansion of clinical services, fewer dispensing errors, and decreased need for floor stock medications.²⁵

The growth of health systems has created the opportunities for departments of pharmacy to become involved managing the medication in ambulatory clinics and infusion centers. Many medication regimens that initially began as inpatient regimens are now routine administrations in the outpatient setting. Increasing demands for proper oversight of medication accreditation bodies, concerns for medication errors, growing sophistication in treating complex diseases in the ambulatory setting, and the increased cost of these medications, allow pharmacists to integrate themselves both operationally and clinically in these settings. Pharmacists and pharmacy technicians have become integral in the preparation and proper administration of such therapies.

RISE OF TECHNOLOGY TO ASSIST DRUG DISTRIBUTION

As medication options continue to expand, the personnel demands of maintaining the unit dose method and complex distribution models also increase. Computers and other technology have helped pharmacists respond to this demand.

One technological advance that is on the decline, due to the decrease in centralized distribution systems, is the use of robots to fill medication carts. These robots are centralized automated dispensing devices that typically contain a medication selection station, a bar-code reader, and packaging and bar-coding equipment. Through the use of bar-code scanning, the robot selects the appropriate medication and number of doses for a medication drawer.²⁶ Robotic fill technology supports a centralized model of drug distribution, where carts are filled automatically in a single location. The computerized information from the pharmacy patient profile system is transferred to the robotic dispensing system before filling. Once started, a bar-code label for each patient is generated and placed on a medication bin. These bins are placed on a conveyor belt, and the patient label is read by a scanner. The robotic filling device immediately recognizes the specific patient's medication needs, picks those medications, and places them in the bin. Once completed, the conveyor belt starts and advances the next bin. The process starts all over again, continuing until all medication carts are filled.

The benefit of the robotic fill system is that it replaces the tedious manual cart fill. Another benefit is its accuracy, as the use of bar codes removes confusion over sound-alike drug names, skipped medications, or errors in choosing the wrong strength. It also frees up technician and pharmacist time and overall inventory costs are reduced, compared to an ADC or pharmacy satellite, because medications are stored in the central pharmacy and not throughout the institution.²⁷

The downside is that special preparation is needed before medications can be loaded into robotic filling systems. All medications need to be placed in unit dose packages that can be read and handled by the robot. This can take significant resources and effort on the part of the pharmacy. In addition, robotic breakdowns or routine maintenance require pharmacy staff to return to filling medication carts by hand.

For that reason and others, ADCs are used frequently in medication distribution to patient care areas. To replenish the stock in ADCs and provide patient-specific doses, carousel technology provides an automated inventory management technology. *Carousels* are an increasingly popular technology in larger hospitals used for medication storage and dispensing from the central pharmacy.⁹ The advantages of a carousel dispensing technology (CDT) is decreased space requirements for medication inventory storage, perpetual inventory management, and improvement in technician efficiency and accuracy.²⁸ Multiple software applications are now available to manage inventory and control the workflow of the technician running the carousels, which can automate first dose and stat medication dispensing as well as ADC replenishment processes. The carousels can also directly order medications from the wholesaler. Carousel workflow includes the machine shelves rotating to the correct shelf based on a signal from the CPOE system or another electronic signal to pick a medication. The appropriate bin storing the medication is lit, the medication is picked, and the bar code scanned to ensure the appropriate product has been selected. Because this whole process is automated, medications can be stored randomly throughout the carousel. This will assist in minimizing medication errors due to look-alike/sound-alike drugs. Carousel inventory is managed by designated minimum and maximums that determine when the product is replenished and how much product should be ordered from a wholesaler or supplier. Incorrect counts can lead to stock-outs of needed product or excess inventory costs.

An ADC is a point-of-use medication storage device located in patient care areas designed to replace traditional floor stock systems and unit dose cart exchange systems (**Figure 7-5**). They allow nurses to have quick access to medications but provide accountability by having an audit trail for all medications removed. Most systems have some form of user identifier or password to restrict access. ADCs are linked to the CPOE and MAR systems to allow removal of medications only after a pharmacist has reviewed the order. This is referred to as a profile system.

The advantage of ADCs is that they permit quick order removal by nursing while still maintaining pharmacy control over the medication-use system. When linked to the pharmacy drug profile, pharmacists can manage access to first doses of new drug orders. Another advantage is that waste is reduced with ADCs because the nurse needs to remove only a dose from the cabinet when it is needed. This provides more accurate patient charges and minimizes the number of credits processed, because doses are subsequently administered upon removal.

KEY POINT . . .

A major disadvantage of the ADC system is that it increases drug inventory on nursing units, and it places some of the burden of medication use back on the nurse.

. . . SO WHAT?

It is important for pharmacists not to forget the evolution of medication-use systems. Pharmacists became involved because control over medication use was inadequate, errors were made, nurses were overburdened, and a lot of waste occurred. When adopting and using medication dispensing technology, policies and procedures must authorize pharmacy oversight for medication use and reduce cognitive burden on nurses.



FIGURE 7-5. Picture of an automated dispensing cabinet. This ADC has a computer monitor for access to patient records and locked medication drawers.

Source: Photo courtesy of BD (Becton, Dickinson and Company), Franklin Lakes, NJ. Used with permission.

Another advantage of the ADC is the ability to control narcotic use. The ADC can provide tracking required by the DEA and can store the narcotics in a safeguarded location where distribution is limited. Drawer types can be configured to manage access from only housing the medication of interest. Nursing can be required to complete blind counts of the inventory following removal of the drug. This will allow for accurate inventory count and the ability to detect discrepancies quickly. The review of removals by pharmacy and nursing can also be helpful in detecting diversions, since all transactions and removals are recorded.

The major disadvantage of the ADC system is that it is similar to the floor stock system, which reduced pharmacy oversight of medication use. This could increase medication errors compared to the unit dose system because nurses have access to many more medications when they open a matrix drawer, although the evidence of this is not clear. Other disadvantages are that it increases drug inventory on patient care areas and potential for nurse queueing at the machine. It also places some of the burden for medication use back on the nurse.

Some of these disadvantages have been minimized by linking ADC systems with pharmacy information systems. Pharmacists at computer terminals working from up-to-date patient-specific profiles now control ADCs on the floor. Nurses can gain access to medications only when they log into the system with a unique password or by using bio-ID scanning of fingerprints. Nurses are guided by a computer screen on the ADC system that matches the patient of interest with medications contained in the cabinet.

Since the adoption of BCMA, charge on administration has replaced ADC charges upon removal. In the past, when the nurse removed a drug and closed the cabinet drawer, the patient was automatically charged for the dose and the inventory was decremented by what was removed. The advantage of charge on administration versus charge on dispense is that there are fewer credits to process, and patients are charged only for what they receive.

ADCs are also utilized in perioperative areas. One such use of an ADC is an anesthesia-focused machine that allows a licensed independent provider (LIP) access to operating room-specific medications while managing patients during procedures or surgeries. The provider has access to all medications during the case, but the machine locks to securely store the medications when the case is finished.

The operating room area is high risk for medication errors due to the lack of double and triple checks by pharmacy and nursing. Often, a single person orders, prepares, and administers the medications. As a result, many technologies have been developed to promote patient safety. One such technology is a label-generating machine that scans a medication vial, reads aloud the medication name and concentration, and subsequently prints a label (**Figure 7-6**). The announcement of the medication name is intended to serve as a double-check that the LIP has selected the correct medication before administration. The safe label system is generally installed on the anesthesia cart (often an ADC) to become a part of the natural workflow.

Medication tracking systems from several vendors have started to penetrate the market. These technologies provide data that previously required manual collection or were not available. Medication tracking systems help prevent missing doses, support better communication with other departments, identify inefficiencies in dispensing and delivery processes, and improve patient outcomes in time-sensitive situations.

FUTURE OF THE MEDICATION-USE SYSTEM

As technology progresses, it will continue to automate the many manual tasks involved with the medication distribution system. Although it still takes time to fill the medication cart (if it is done manually), replenish the robotic dispensing device, or refill the ADC, automation will further decrease the number of people involved with the dispensing of the medications. It will increase not only the amount of data captured that will be useful in ensuring medication errors are reduced, but it will also increase efficiency.



FIGURE 7-6. Picture of Codonics Safe Label System (SLS). Vials can be scanned in the perioperative area to print a label and double-check that the provider has pulled the correct medication before administration to the patient.

Source: Photo courtesy of Codonics Safe Label System (Codonics, Middleburg Heights, OH). Used with permission.

In the future, drugs may be provided to nursing units from an off-site pharmacy affiliated with the institution or it can be outsourced to wholesalers or other providers (**Figure 7-7**). Most pharmacies will likely maintain distribution systems that have characteristics of a centralized and decentralized system, along with ADCs. However, outsourcing of medication distribution to wholesalers may also become more widespread, which will dramatically change the medication distribution systems and the role of the pharmacist. Presently, wholesaler outsourcing may be limited to delivering totes specific for an ADC. Depending on various state laws, outsourcing can expand to where wholesalers go to nursing units and replenish the ADCs, reducing the amount of time that a pharmacy department needs to be involved. The wholesaler may even own the inventory and charge for it when the patient uses it. This is especially true as hospitals acquire more remote physician clinics. As opposed to being stocked by the pharmacy, having wholesalers deliver the medication straight to the clinic is much more efficient.

Bar-code technology will continue to be important in medication distribution. Bar codes help pharmacists track medication use and ensure that patients receive the correct

KEY POINT . . .

Studies have demonstrated that a tech-check-tech system for checking unit dose carts is as good as, if not better than, a pharmacist checking a technician.

. . . SO WHAT?

Some pharmacists are still resistant to the idea of systems that allow technicians to check the work of technicians. One concern is that technicians lack the professional training and experience to adequately monitor the quality of the dispensing process. Studies have shown that this is not the case in some situations. Indeed, pharmacists may be overqualified for this task and better used elsewhere for improving the medication-use process.

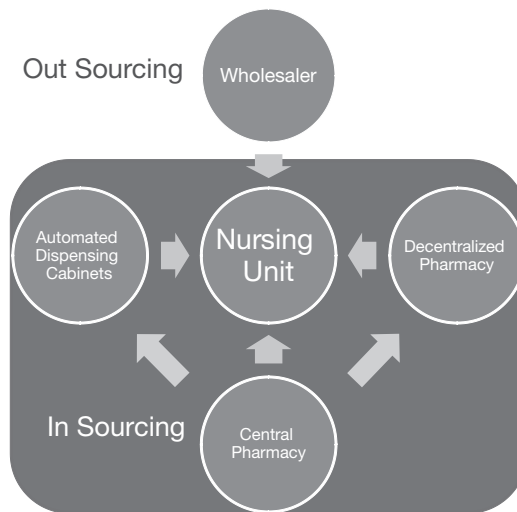


FIGURE 7-7. Sources of medications for nursing units. Nursing units in U.S. hospitals receive medications from a variety of sources—both within and outside of the hospital. Within the hospital (i.e., insourcing), medications can be dispensed from the centralized pharmacy, decentralized satellite, or automated dispensing cabinet. Outside of the hospital (i.e., outsourcing), medications may be directly delivered to the nursing unit from a wholesaler or other supplier.

medication. Bar codes also help robots and other technologies read package labels and ensure patients are charged only for medications received.

Technicians will also continue to play a large role in the medication distribution system. Studies have demonstrated that a tech-check-tech system for checking unit dose carts is as good as, if not better than, a pharmacist checking a technician.²⁹⁻³¹ The pharmacist's value lies in using his or her professional judgment in various ways including the profiling of medication orders, monitoring the medication-use process, taking medication histories, and conducting discharge counseling. The technician's value lies in the distribution process.

REQUIREMENTS OF ANY GOOD MEDICATION DISTRIBUTION SYSTEM

As pharmacy medication distribution systems evolve, pharmacists must demand several requirements of all new systems. The first is that pharmacists must always maintain quality control over drug use in institutions where patients are assured of receiving the right drug at the right time in the right way. This means that pharmacists need to be involved in efforts to prevent the diversion of drugs, reduce medication errors and waste, minimize adverse drug events, and ensure that drugs maintain potency through proper storage and handling.

Another requirement is that any system must be efficient in how it achieves drug-use control. Thus, trade-offs may need to be made in some traditional practices that may not be cost effective. For instance, many distribution activities traditionally performed by pharmacists, such as checking medication carts, might be better delegated to pharmacy technicians.

Finally, current and future medication distribution systems must always attend to the needs of those served by these systems—patients, physicians, and nurses. Therefore, the systems need to reduce the effort and inconvenience associated with the medication-use process and enhance patient outcomes.



SUMMARY

The unit dose system and the development of automation for drug distribution have had a profound impact on elevating the practice of hospital pharmacy. The unit dose system reduces medication errors and supports the concepts of clinical pharmacy. Technology has further enhanced the distribution of medications, allowing pharmacists to become more involved with patient care. The use of technology should further improve medication use by helping maintain pharmacist oversight of the process and allow the pharmacists to better care for patients' medication needs.

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CHAPTER REVIEW QUESTIONS

1. **Under what circumstances should pharmacists give up their responsibility to control drug distribution in healthcare institutions?**
 - a. Whenever medications can be delivered cheaper and faster than from a pharmacist-controlled system.
 - b. As soon as possible because the future of pharmacy practice is clinical pharmacy.
 - c. Never. Distribution is a fundamental responsibility of pharmacists.

Answer: c. The role of pharmacists is drug-use control. Giving up control of the distribution process would be counter to the profession's mission. Drug-use control is more than getting medications to the patients fast and cheap, and clinical pharmacy is complemented by the distribution process.

2. **Improvements in drug distribution have led the way for clinical pharmacy services.**
 - a. True
 - b. False

Answer: a. True. When pharmacists accepted responsibility for and improved the distribution of drugs in health systems, they were able to establish credibility as experts in drug-use control. Clinical pharmacy services were built upon that credibility.

3. **A centralized pharmacy is no longer needed if satellite pharmacy services are provided throughout the hospital.**

- a. True
- b. False

Answer: b. False. Satellite services must still be supported by centralized services. Centralized pharmacies typically provide preparation of refill medications, inventory control, managerial support, and other services that satellites cannot easily and efficiently provide.

4. **Emergency medications are made available throughout the hospital in tamper-evident containers called _____.**

- a. Lock boxes
- b. Crash carts
- c. Tackle boxes

Answer: b. Also known as code carts, these containers are distributed throughout the hospital to have critical medications and supplies available to respond to emergencies. They are tamper evident to reduce the temptation for healthcare personnel to borrow medications from the cart for nonemergency situations. If tampered with, the cart must be immediately replaced with another cart that is fully stocked with supplies and medicines.

5. **Some type of electronic identification system such as bar codes is needed on all unit-of-use packages to support BCMA.**

- a. True
- b. False

Answer: a. True. BCMA software need bar codes to identify medications. If unit-of-use packages with bar codes are not available from the manufacturer, they must be packaged in the pharmacy from bulk medicine containers.

6. **Identify the steps in the medication-use process when safety may be enhanced via bar-code scan.**

- a. Documentation of administration
- b. Checking of final medication product before sending to floor for administration
- c. Removal from automated carousel
- d. ADC replenishment
- e. All of the above

Answer: e. All of the above. All of the listed steps in the medication distribution footprint can be safer processes when a bar-code check is incorporated.

7. **ADC use has declined over the past 10 years.**

- a. True
- b. False

Answer: b. False. ADC's prevalence has increased over the past 10 years, particularly in larger hospitals.

8. **What are the requirements of a good medication distribution system?**

- a. Safety
- b. Efficiency
- c. Customer satisfaction

- d. Cost effectiveness
- e. All of the above

Answer: e. All of the above. Each of these attributes need to be present and regularly evaluated in the distribution system.

9. Over the last 20 years, technology has increased across the medication-use system. This has led to a safer system.

- a. True
- b. False

Answer: b. False. While technology has removed many manual tasks associated with preparing and dispensing medications, it has also introduced new errors into the system. While one might agree that it is safer, errors still occur and one cannot rely on technology solely for reduction in errors.

10. Because of changes to the medication-use system, pharmacy technicians can be optimally used within various distributional practices.

- a. True
- b. False

Answer: a. True. Pharmacy technicians have been shown to intercept at least as many errors as pharmacists, and this can allow pharmacists to spend more time with patients.

11. Pharmacy carousels improve the management of inventory within central pharmacy.

- a. True
- b. False

Answer: a. True. Carousels allow for perpetual inventory, knowing the exact count for a drug at all times. This will allow one to place an order when inventory numbers become low and the order will contain just what is needed. Carousels also allow for random placement of medications, minimizing the chance for look alike–sound alike errors.

CHAPTER DISCUSSION QUESTIONS

1. Compare the advantages and disadvantages of floor stock, patient prescription, and unit dose systems from the pharmacist and nurse's perspective.
2. Describe the advantages and disadvantages of utilizing a primarily decentralized (i.e., ADC based) model from a medication safety and customer service standpoint.
3. Clinical pharmacy in institutions did not blossom until pharmacists started taking greater responsibility for drug use. What lessons does this have for pharmacists practicing in community pharmacy settings?
4. Describe how access to the medication profile has impacted pharmacy's role in patient care.
5. Review the various technologies that are in place to automate the medication-use process, describing the advantages and disadvantages of each one.
6. What are areas of the medication-use process that can still be optimized?
7. What aspects of the medication-use process still need to be researched to understand its impact on operations or patient care?

Controlled Substances Management

George J. Dydek and David J. Tomich



LEARNING OBJECTIVES

After completing this chapter, readers should be able to:

1. Discuss the federal and state laws governing controlled substances in institutional pharmacies.
2. Identify organizations involved in regulating, managing, and providing guidance in controlled substances use.
3. Define key terms associated with controlled substances management.
4. Explain and describe the critical role and responsibility that pharmacists play in the oversight of controlled substances.



KEY TERMS AND DEFINITIONS

- **Code of Federal Regulation (CFR):** A set of general or permanent rules that are published in the Federal Register by the federal government. The regulation is divided into 50 titles encompassing executive departments and agencies covering broad areas subject to federal regulation.
- **Controlled Substance Act (CSA):** Also known as the Comprehensive Drug Abuse Prevention and Control Act of 1970, the CSA is the federal government's drug policy. It governs the manufacturing, importation, posses-

sion, and distribution of certain substances that have been classified into five schedules based on their potential for abuse and accepted medical use in the United States.

- **Drug Enforcement Administration (DEA):** A law enforcement agency under the Department of Justice that is responsible for enforcement of the U.S. drug policy as required under the CSA.
- **Failure mode and effects analysis (FMEA):** A systematic approach of examining and analyzing a process to determine potential areas where errors or failures may occur (failure modes) and determine the effects (effects analysis) of those failures on a process so as to identify opportunities for improvements.
- **Institute for Safe Medication Practices (ISMP):** A nonprofit organization with the mission of enhancing patient safety through education, collecting and analyzing adverse drug events, disseminating medication safety information, collaborating with health-care organizations, and conducting research.
- **Medication-use evaluation (MUE):** An examination of a specific medication, most often within the context of a defined healthcare system. It is a method usually incorporated into an organization's performance improvement program that examines the utilization of a medication and its effects on patient outcomes.

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- **Policies and procedures:** A set of written requirements dictated by an organization (policies) that provide the foundation for the written procedural instructions in an organization (procedures).
- **Power of attorney authorizations:** A legal document that allows another person to act on one's behalf (i.e., allowing another pharmacist to order or receive controlled substances).
- **Stop order:** An order that automatically discontinues a medication based on pre-established parameters (e.g., time, clinical conditions).
- **Taper order:** An order that changes the dose of a medication; the dose is either progressively decreased or increased based on pre-established parameters (e.g., time, clinical conditions).



INTRODUCTION

Pharmacy is responsible for all medications in an institutional pharmacy practice setting.¹ The obligation in oversight for absolute accountability for medications is most critical in the management of controlled substances. This chapter will explore and review the management of controlled substances within healthcare systems. It is not intended to give a detailed description of applicable federal or state laws and regulations regarding the management of controlled substance medications (subsequently referred to as *controlled substances*). Rather, this chapter will take a medication-use systems approach in examining the management of controlled substances in the health-system environment. Strategies and resources for pharmacists are offered.

The *medication-use systems approach* allows for the systematic examination of controlled substances within an organization—from selection and procurement through storage, inventory management, dispensing, administration, surveillance, and system evaluation. ASHP provides guidelines to help pharmacists in the oversight of controlled substances in patient care areas that prevents diversion without inhibiting patient care services.² Another good source for best practices in controlled substances diversion is a review by Martin et al. that provides examples of controlled substances diversion incidents and ways of avoiding similar situations.³

Several factors influence the necessity for controlled substances management. Abuse, misuse, and associated costs of controlled substances impact all segments of our society, especially in the area of prescription medications. The death rate from drug overdose in the United States doubled from 1999 to 2013, which was primarily attributable to prescribed controlled substances.⁴ Diversion and abuse of prescription opioids increased steadily from 2002 to 2010, although it has generally plateaued after 2010. Potential factors slowing the misuse include improvement in prescribing practices through prescriber education and clinical guidelines, prescription-drug monitoring programs, and abuse-deterrent opioid analgesic formulations.⁵ Despite some recent success, the problem of abuse and misuse of controlled substances is an ongoing concern of institutional pharmacists.

Three areas of pharmacists' oversight are critical to safeguard the appropriate utilization of controlled substances within healthcare systems:

1. Pharmacists must ensure the adherence to all federal and state laws and regulations.
2. They need to influence the safe use of controlled substances with minimal medication errors resulting in adverse patient outcomes.
3. Pharmacists must ensure that controlled substances achieve optimal health for patients.

Each of these factors will be discussed in the following sections of this chapter.

FEDERAL AND STATE LAWS AND REGULATIONS

Federal and state laws and regulations are overriding influences on the management of controlled substances in the healthcare environment. The principal federal law regulating controlled substances is the **Controlled Substance Act (CSA)**, also referred to as Title II of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, under Title 21 United States Code, starting at Section 801.⁶ The **Drug Enforcement Administration (DEA)** is the federal entity charged with enforcing and implementing the CSA under Title 21, **Code of Federal Regulations (CFRs)**, starting at Part 1300.⁷ The main mission of the DEA is to work in concert with state agencies and other federal agencies (e.g., Food and Drug Administration [FDA]) to prevent the diversion of controlled substances for illicit reasons. Additionally, the DEA provides an informative manual targeted for pharmacists that can be readily retrieved from their website.⁸

Controlled substances are classified according to their potential for abuse, accepted medical use, and potential for physical or psychological dependence, which places them into different schedules (I–V). A list of these classified medications can be viewed through a hyperlink from the DEA website.⁹ Most state laws and regulations regarding controlled substances mirror the CSA, although some may have more stringent requirements. They can never be less stringent than federal requirements under the CSA.

It is beyond the scope of this chapter to detail variations between federal and state laws regarding these medications. Pharmacists can obtain guidance about specific state laws and regulations regarding controlled substances from regulatory agencies in the state where they practice. Another source of information regarding some state and national activities involving controlled substances can be found at a website maintained by the National Association of State Controlled Substance Authorities.¹⁰

PATIENT SAFETY

Controlled substances are a significant threat to patient safety due to potential errors and the complexity of pharmacotherapy. Two nongovernmental organizations place a major emphasis on patient safety associated with the use and management of controlled substances.

One organization is the **Institute for Safe Medication Practices (ISMP)**. It has designated controlled substances—narcotics/opioids in several dosage forms (intravenous, transdermal, and oral preparations)—as *High Alert* medications.¹¹ This means that errors involving high alert medications have a greater risk of causing negative outcomes for patients. This designation for narcotics/opioids resulted because of numerous medication errors reported through the ISMP National Medication Error Reporting Program. Medication errors involving controlled substances are more frequently reported nationally, with morphine second only to insulin in the number of errors contributing to patient morbidity and mortality.¹² The ISMP Medication Safety Alert program for acute care environments continues to describe problem errors relating to the use of patient-controlled analgesia specifically, narcotic toxicity due to inappropriate dosing.¹³ Additionally the ISMP publishes and readily updates a list of drugs with similar sounding names that can be confused with each other, resulting in errors. That list includes several controlled substances.¹⁴

Another organization that focuses on safe use of controlled substances is The Joint Commission. Through its sentinel event reporting system, The Joint Commission has identified opioid-related adverse drug events impacting hospital inpatients and published guidance for actions to be taken to avoid events.¹⁵ Recommended evidence-based actions include implementation of effective management processes, use of technology, education

and training for all healthcare staff, and standardization of patient care tools.

Complexity of Pharmacotherapy

The inherent complexity of pharmacotherapy and medication delivery systems can lead to negative health outcomes for patients. Many new formulations of older agents (e.g., morphine in sustained-release formulations, newer novel administration devices, formulations to deter substance abuse, new FDA-approved medications working on newly discovered neurotransmitters or changes in the Schedule classification of controlled substances) will constantly challenge pharmacists in the management of controlled substances.¹⁶ An example in the complexity of medication delivery systems and the effect on different

patient populations is in an FDA decision in March 2009 to remove from the market an unapproved version of morphine concentrate liquid preparations widely employed in the hospice patient population.¹⁷ The FDA subsequently reversed their decision after widespread outcries from the healthcare community. The health-system practicing pharmacist will continue to be challenged as new controlled and non-controlled agents are developed with novel pharmacologic applications and delivery systems.

KEY POINT...

Controlled substances have a greater risk of causing negative outcomes for patients.

...SO WHAT?

Controlled substances are typically stocked in nursing units to make them readily available to patients. Much of controlled substance use is “as needed,” subject to the professional judgment of nurses. Pharmacists should monitor the outcomes associated with controlled substance use within their institution.

SELECTION OF CONTROLLED SUBSTANCES

Formulary

The pharmacy and therapeutics (P&T) committee selects all medications, including controlled substances, in most health systems. When any controlled substance medication is considered for inclusion into a formulary, a detailed evaluation of the medication should be conducted. Data on the safety, efficacy, toxicity, potential for adverse events and abuse, and pharmacoeconomics—related to the population served by the health system—are reviewed. Some of the criteria considered include the following:

- Location within the health system, other than the pharmacy, where the controlled substance will be stored, considering appropriateness of use based on the patient population and clinical utilization.
- Storage requirements for the controlled substances based on manufacturer requirements, such as refrigeration. As controlled substance inventory goes up due to increased utilization and/or increase in formulary additions, the pharmacy needs to consider immediate needs and project ahead for appropriate space.
- Physical security requirements at the location to ensure federal or state standards are met.
- Appropriate stocking levels both within the pharmacy and outside in patient care areas.
- The healthcare staff's authorized access to the medication.
- Requirement for any prescribing restrictions based on providers' scope of practice.

- Incorporation of the controlled substances into any prescribing or clinical guidelines (i.e., pain guidelines).
- Prescribers' specific requirements for medication ordering (i.e., **stop order** requirements or **taper order** requirements).
- Healthcare staff and patient education requirements on the use of the controlled substances prior to release into the institution.
- Any new policies and procedures that need to be addressed with the addition of the controlled substances.
- Utilization follow-up based on formulary selection criteria on safety, efficacy, toxicity, potential for adverse events and abuse, and pharmacoeconomics.

KEY POINT . . .

Failure mode and effects analysis (FMEA) or a similar risk identification and assessment process are useful when evaluating the controlled substances for formulary addition and prior to procurement and distribution within a health system.

. . . SO WHAT?

FMEA attempts to be proactive in addressing problems with the medication-use process. Rather than waiting for a problem to occur, FMEA in controlled substance systems seeks to identify and address potential problems that might lead to a negative patient health outcome or a state or federal agency investigation for inadequate oversight and documentation of controlled substance inventory.

Risk Assessment

Use of a **failure mode and effects analysis (FMEA)** or similar risk identification and assessment process is useful when evaluating the controlled substances for formulary addition and prior to procurement and distribution within a health system.^{18,19} FMEA examines the potential for failures by identifying, classifying, and assessing the impact of failures on the system. *Failure modes* are any errors or defects in a process, design, or item, especially those that affect the customer, and can be potential or actual. *Effects analysis* refers to studying the consequences of those failures. Pharmacists can use FMEA to identify and examine potential deficiencies in medical processes or oversight of federal and state legal requirements associated with physical security, accountability, documentation, and audit trail. A critical analysis of the processes involved in the medication-use system for controlled substances can identify risk reduction strategies to enhance patient safety.

PROCUREMENT OF CONTROLLED SUBSTANCES

Federal Registration Requirements

Procurement of controlled substances requires that health-system pharmacies register with the DEA by submitting DEA Form 224, Application for New Registrant.²⁰ The registration is required to be renewed every 3 years with both the initial and renewal involving fees. The procurement of Schedule IIs requires the use of DEA Form 222. The pharmacist in charge of the health-system pharmacy needs to acquire a complete understanding of federal requirements for procurement and processes within the medication-use system to ensure integrity in accountability and documentation of controlled substances.⁸

INVENTORY AND STORAGE MANAGEMENT OF CONTROLLED SUBSTANCES

Inventory and Record Requirements

Once the controlled substance has been procured, the pharmacist must ensure compliance with regulations pertaining to accountability and documentation. The inventory system must allow for an audit trail of complete and accurate documentation of the controlled substance through the medication-use system from the point of procurement and receipt in the pharmacy, through storage and distribution points within the institution, to administration to a patient. Certain records must be maintained for 2 years in paper or electronic format to be readily retrievable on demand by state or federal inspectors. Records for Schedule II substances are segregated from all other records, whereas records for Schedules III–V substances may be kept separate from other records or mixed with other records if kept in a readily retrievable form. Federal law and regulations require the following records to be maintained:

- Official order forms such as the official record of receipt and sale for Schedule II controlled substances, DEA Form 222.
- **Power of attorney** to sign for DEA order forms.
- Receipts and invoices for Schedule III–V controlled substances.
- Initial inventory taken when a new DEA registration is required. The CFR requires the date and time of the initial inventory be documented; the name of the drug, strength, and dosage form; the number of units or volume; and total quantity of the controlled substance.
- Biennial inventory is conducted following the initial inventory, with the same required information as in the initial inventory. An actual count is required for all Schedule II controlled substances. The inventory for Schedule III–V controlled substances allows for an estimated count, unless the container holds more than 1,000 dosage units, then an exact count must be made.
- Records of controlled substance distribution and dispensing records (i.e., prescriptions).
- Records, if needed, relating to theft or loss (DEA Form 106).
- Inventory of controlled substances surrendered for disposal (DEA Form 41).
- Records of any transfers of controlled substances between pharmacies.
- DEA registration certificate.

KEY POINT . . .

A controlled substance inventory system must allow for an audit trail of complete and accurate documentation of the controlled substance procurement, receipt, storage, distribution, and use.

. . . SO WHAT?

Imagine that you are a director of pharmacy standing before a DEA representative who has responded to a report that controlled substances have been diverted from your pharmacy's inventory. Now imagine how much worse the situation would be if you could not identify the point where the diversion occurred within the system because the institution's record keeping for controlled substances was inadequate.

All of the above records must contain the drug name, drug strength, dosage form, number of units or volume, and total quantity of the controlled substances.

Physical Security and Storage

Federal requirements for physical security for controlled substances require that the medications be in a “securely locked, substantially constructed cabinet” to deter theft and diversion. Pharmacies are allowed to place the controlled substances among the non-controlled medications as long as there are barriers to theft of the controlled substances.⁸ This requirement provides a lot of latitude in where the controlled substances can be stored. Pharmacists need to evaluate the storage location of all controlled substances within their health system to consider the level and type of physical security warranted. In some cases, a locked cabinet, with minimal stock levels, and limited access to healthcare staff may be sufficient security. In other cases, the requirement for a safe with intrusion detection devices and alarm systems may be warranted. The following are suggested factors to consider in determining the level of security required by the CFR Part 1301²¹:

- Location of the storage site (e.g., pharmacy, inpatient wards, surgical suites, ambulatory clinics).
- Level of activity of the storage site for controlled substances (e.g., bulk storage in the pharmacy, hospital ward, or clinic stock).
- Quantity of controlled substances expected to be stored at the site.
- Dosage form of controlled substances handled at the storage site.
- Level of physical security that the container provides that will be utilized for storage of the controlled substances (e.g., safe, fixed cabinet, movable cabinet, automated storage and dispensing device).
- Policies and procedures for restricting access to the storage site (e.g., authorized personnel, access code management, key control, safe combination procedures).
- Adequacy of electronic detection, monitoring and alarm systems (e.g., cameras, motion sensor detectors, biometric identification).
- Amount of unsupervised access, or potential for unsupervised access and procedures for handling patients and visitors.
- Amount of oversight of healthcare staff, whether they have immediate access to the controlled substances or not.
- Audit capability and inventory management of controlled substance at storage site.
- Review of applicable state laws and regulations as well as institutional policies and procedures.

McClure et al. conducted a survey that indicated a wide variation among health-system pharmacy directors in implementation of recommended prevention and detection strategies for controlled substances diversions in hospitals, to include basic physical security requirements.²²

Automated Storage and Distribution Devices

Automated storage and distribution devices greatly enhance the process of controlled medication distribution within health systems in both patient safety and inventory control. The devices permit better inventory control by allowing electronic documentation of all controlled medication use. All access to storage of drugs is limited to those with unique passwords that permit easy identification of individuals. User identification of access to the storage devices provides an audit trail if any discrepancies of records occur. As more

health systems adopt bar-code technology applications at the point-of-administration, the ability to regulate controlled drug use will improve. ASHP provides considerations for requirements in automated storage and distribution devices.²³

Disposal of Controlled Substance Medications

When controlled substances need to be disposed of due to expiration, damage, or for other quality control reasons, they must be segregated and inventoried separately from all other drugs. Title 21 CFR, Part 1317, requires that the inventory for these medications include the inventory date, drug name, strength, dosage form, total quantity or total number of units or volume, the reason for maintaining the substance in the disposal inventory, and whether the substance can be used in the manufacturing of other controlled substances. A company that disposes of expired medications (a reverse distributor) may be used for controlled substances, as long as that distributor is registered with the DEA. Pharmacists can contact the local DEA Diversion Field Office to determine which reverse distributor is registered with the DEA. Complete inventory documentation of any transfer of disposed controlled substances needs to be retained. In a national effort to decrease the availability of unused controlled substances, the DEA allows hospitals and clinics with an on-site pharmacy to establish collection or drop-off sites for community members. Pharmacists need to ensure they are in compliance with DEA requirements as defined in Title 21 CFR, Part 1317—Disposal.²⁴

ORDERING AND DISPENSING OF CONTROLLED SUBSTANCES

Medication Orders

The institution pharmacist practices in a different environment with regard to medication orders and dispensing than the pharmacist practicing in the ambulatory (outpatient) environment. Typically, the pharmacists practicing in health systems will find themselves in the position of reviewing medication orders from a provider (prescriber) entering that order into a pharmacy informatics system to be processed and then dispensed directly to the provider, nursing staff, or released from an automated storage device.

The ordering of medications is defined under Title 21 CFR, Section 1300, and further covered under Section 1306. Title 21 CFR, Section 1300, defines a *prescription* as a means of ordering medication intended to be dispensed for a patient who is the ultimate user. The regulation goes on to clearly state that a *prescription* does not cover medication orders that are written for the purpose of being dispensed for immediate administration to a patient in a hospital setting. Pharmacists dispensing a prescription for controlled substances for patients in an ambulatory (outpatient) setting have strict requirements for container labeling. These same requirements are not required for hospital dispensing from a federal CSA perspective.^{25,26} Pharmacists should be aware that specific requirements for controlled substances dispensed in institutions may be covered within state law or regulations and institutional policies and procedures. Applying Joint Commission requirements for medication orders and labeling of dispensed medications of controlled substances within a hospital will more than adequately cover any federal requirements.

In an institutional practice, individual practitioners (physicians, mid-level practitioners) employed at an institution or hospital may conduct medication-related activities such as administering, dispensing, or prescribing controlled substances under the hospital's DEA registration. These activities are allowed as long as the practitioner is engaged in the usual course of professional practice while in the employment of the hospital and allowed by state law and regulations. Pharmacists are advised to seek out state law and regulations regarding mid-level practitioners' prescriptive authority. Additionally, health systems may

have established formulary prescribing restrictions placed on controlled substances that are based on clinical practice guidelines or through the hospital's credentialing process of restricting certain prescribing privileges to individual practitioners.

Electronic Prescribing

There is a continuing movement and emphasis across the nation to migrate an electronic format and utilize the electronic medical record within an institutional environment. Certainly from a patient safety perspective, the migration of medication ordering has been identified as a major tool to prevent medication-related errors. The DEA has authorized the facsimile of Schedule II substances prescriptions since 1994. This authorization is allowed if an original prescription is presented at the time of actual dispensing of the controlled substances. Exceptions to this requirement for an original prescription are for medication orders related to home intravenous infusions for pain therapy, patients in long-term care facilities, and patients in hospice care. Facsimile prescriptions for Schedule III–V substances are authorized without the requirement for an original prescription to be presented at the time of dispensing. With the advent of physician computer order entry and the strong movement within health systems across the nation to adopt this technology, federal/state laws and regulations regarding controlled substances have and will continually need to address the electronic transmission of medication orders in the absence of paper. Title 21 CFR, Section 1306 and Section 1311, define the requirements for electronic orders and prescriptions to ensure appropriate security requirements in the electronic transmission of controlled substances prescriptions.^{27,28}

KEY POINT . . .

Physician computer order entry within health systems will require changes in both federal and state laws and regulations.

. . . SO WHAT?

The electronic transmission of orders for controlled substances offers both opportunities and risks. Electronic order transmission can permit more accurate communication of orders and better record keeping. However, it can also lead to new ways of diverting drugs outside of approved channels. Pharmacists' expertise will be necessary to ensure that the negatives of computerized prescriber order entry do not outweigh the positives.

ADMINISTRATION OF CONTROLLED SUBSTANCES

As has been highlighted previously, the three primary factors requiring increased scrutiny of controlled substances are attributable to federal and state laws and regulations, patient safety, and the complexity of pharmacotherapy. Pharmacists must take an active role in working primarily with the nursing staff to reduce the risk of controlled substances diversion and enhancing patient safety at the point of administration. The complexity of pharmacotherapy is certainly contributory to the environment of increasing the potential for medication errors, with multiple medications and dosage forms, medications with look-alike and sound-alike names, and the increased utilization of infusion devices. Risk reduction strategies for minimizing medication errors prior to administration on patient care units include limiting access to the controlled substances; limiting the availability of some products, especially look-alike and sound-alike identified controlled substances; requiring redundancies involving a double-check system; educating the healthcare staff and patients; and monitoring patients.²⁹

EVALUATION OF CONTROLLED SUBSTANCES

Medication-Use Evaluation Program

A **medication-use evaluation (MUE)** program can provide pharmacists with a mechanism for examining the utilization of controlled substances within the health system. A MUE is a method usually incorporated into an organization's performance improvement program that examines the utilization of a medication and its effects on patient outcomes.³⁰ The MUE process can be a tool to study the use of controlled substances throughout the medication-use system or to focus on one particular process of the system. If employed as part of a multidisciplinary program, it can be used to enhance patient safety, ensure compliance with regulation and laws, and most importantly affect patient outcomes.

Controlled Substances Surveillance Program

Controlled substances by definition are medications that have the potential for abuse and diversion within the medication system. The fact remains that in our society the potential for abuse and diversion of controlled substances exists within the healthcare system by all professionals. There needs to be a controlled substances surveillance program that focuses on diversion detection and prevention and subsequent abuse.

Controlled substances surveillance is a required program in which every pharmacist must be actively engaged. Every ambulatory care, outpatient pharmacy, or emergency department setting utilizes the nationally deployed Prescription Drug Monitoring Program assisting in identification and deterring drug abuse and diversion of controlled substances.³¹ In the inpatient setting, the deployment of automated storage and distribution devices previously noted has enhanced inventory control management of controlled substances. These devices not only serve as excellent inventory management tools for controlled substances but can serve as tools in any surveillance program. There are several commercial vendors on the market that offer storage devices with computer software enhancements, data capture, and report capabilities to allow pharmacists in any health system to monitor controlled substances. Wellman et al. describe an efficient computer-assisted surveillance program utilizing data capture from automated storage and dispensing devices.³² Any surveillance system built to monitor controlled substances will invariably have deficiencies. An article by O'Neal describes the inherent flaws in current automated surveillance systems and presents diversion scenarios with some recommendations for resolutions.³³ One recommendation is to ensure that information on the controlled substances surveillance program is readily available for pharmacy and nursing managers. Brenn et al. describe the development of a computerized monitoring program in a pediatric anesthesia area.³⁴ This group capitalized on integrating pharmacy and anesthesia information systems to create a monitoring system that enhanced detection of drug diversion. Any controlled substances surveillance program will not only need to exploit information systems across patient care areas through an automated data collection and analyses tool, but also fully engage all staff members within pharmacy and departments or services outside the pharmacy.

Clinical Practice Guidelines

Pharmacists should not lose sight of the tremendous therapeutic potential that controlled substances offer when used appropriately. The use of clinical practice guidelines provides the opportunity to improve the quality of patient care through appropriate use of controlled substances. This is especially evident in the area of pain management, where there has been a tendency within the healthcare environment to allow strict oversight and fear of abuse and diversion of controlled substances to hinder appropriate patient care. An example of a

clinical practice guideline designed specifically for the use of opiates to treat chronic pain can be found at the American Academy of Pain Medicine.³⁵ The state of Washington has published updated guidelines to assist practitioners in the safe and effective use of controlled substances for the treatment of pain with an expanded focus of addressing special patient populations for chronic non-cancer pain as well as acute, subacute, and perioperative pain management.³⁶ Clinical practice guidelines are part of any MUE program that strives to ensure appropriate utilization of medication and can be used as a tool in a controlled substances surveillance program.

KEY POINT...

There has been a tendency within the healthcare environment to allow controlled substances to hinder appropriate patient care.

...SO WHAT?

Healthcare providers must balance concern about preventing controlled substance diversion with what is best for patients. Ultimately, what is best for patients should always win out.

POLICIES AND PROCEDURES FOR CONTROLLED SUBSTANCES

As with any process within the medication-use system, it is imperative that policies and procedures for controlled substances management be developed and instituted within the organization. **Policies and procedures** are a vital tool in the management of a pharmacy in any health system.³⁷ This is especially evident in the management of controlled substances and needs to address the entire medication management system from selection, procurement and storage, ordering, distribution, and preparation through administration and monitoring. The following are some controlled substances subject areas that need to be addressed in policies and procedures:

- What personnel are authorized to procure controlled substances and under what authority?
- What are the normal and emergency procurement procedures for controlled substances?
- What is the process for receiving controlled substances including staff responsibilities, storage location, and procedures for handling a discrepancy?
- How are inventory management and accountability handled in the pharmacy?
- How are inventory management and accountability handled in patient care areas?
- What are the procedures for distributing controlled substances within the health system from the pharmacy to patient care areas, including staff responsibilities and security of controlled substances during transfer?
- What are the procedures for intravenous compounding of controlled substances including disposal, distribution to patient care areas, and accountability?
- What personnel have authorized access to storage sites?
- How are controlled substances disposed of by the pharmacy personnel or any healthcare provider?
- How are controlled substances returned from patient care areas handled?
- What is the procedure for handling a patient who has a personal supply of controlled substance medications?
- How are controlled substances managed in surgical and anesthesia services areas?

- How are controlled substances managed in regard to automated storage and dispensing devices including staff responsibilities in stocking, quality control, discrepancies, problem solving with users, control of access codes, archiving of data, and surveillance report generation?
- How are significant discrepancies anywhere in the health system handled? What trigger points are used to decide when to engage outside agencies (e.g., DEA, state agencies, law enforcement)?
- What is the process for new employee orientation and ongoing competency assessment for the staff in dealing with controlled substances?

KEY POINT...

It is imperative that policies and procedures for controlled substances management are developed and instituted within the organization.

...SO WHAT?

The risks associated with controlled substances are too great to allow much flexibility in the process. Aside from the real risk to patients, a pharmacist's career is at risk if he or she is careless in the handling or recording of controlled substances. One of the quickest ways to be fired from a job at a pharmacy and/or face legal implications is to be lax with one's responsibility in managing controlled substances. Conscientiously following policies and procedures in this area is essential.



SUMMARY

Controlled substances medications are an integral and important component of many pharmacotherapy plans for patients; at the same time, these medications have increased potential for abuse and misuse, dictating institutional pharmacists' increased oversight. This increased oversight requires compliance with legal aspects of medication management while ensuring appropriate pharmacotherapy. All pharmacy staff must be knowledgeable, competent, and vigilant. The pharmacists' vigilance in the controlled substance medication management system will ultimately enhance patient outcomes.

Controlled substances management will continue to present many challenges for healthcare organizations and society. Institutional pharmacists are the healthcare professionals in the best position to continue to provide leadership in devising effective and efficient management methods for controlled substances management.

SUGGESTED READING

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CHAPTER REVIEW QUESTIONS

1. **Which of the following entities are responsible for the enforcement and implementation of the Controlled Substances Act?**
 - a. The ISMP
 - b. The Joint Commission
 - c. The FDA
 - d. The DEA

Answer: d. The DEA. The Drug Enforcement Administration is the federal entity charged with enforcing and implementing the Controlled Substances Act.

2. **State laws and regulations regarding controlled substances are always the same as those requirements under the federal CSA.**
 - a. True
 - b. False

Answer: b. False. Most state laws and regulations regarding controlled substances mirror the CSA, although some may have more stringent requirements. They can never be less stringent than federal requirements under the CSA.

3. **When any controlled substance medication is considered for inclusion into a formulary, a detailed evaluation of the medication should be conducted.**
 - a. True
 - b. False

Answer: a. True. When any controlled substance medication is considered for inclusion into a formulary, a detailed evaluation of the medication should be conducted. Data on the safety, efficacy, toxicity, potential for adverse events and abuse, and pharmacoeconomics related to the population served by the health system are reviewed.

4. **A controlled substance inventory system must allow for an audit trail of complete and accurate documentation of the controlled substance through the medication-use system.**
 - a. True
 - b. False

Answer: a. True. The inventory system must allow for an audit trail of complete and accurate documentation of the controlled substance through the medication-use system from the point of procurement and receipt in the pharmacy, through storage and distribution points within the institution to administration to a patient.

5. **Schedule II controlled substances are obtained through the utilization of DEA Form 106.**
 - a. True
 - b. False

Answer: b. False. The official record of receipt and sale of Schedule II controlled substances is DEA Form 222. DEA Form 106 is a form used to record theft or loss of controlled substances.

6. **A biennial inventory is conducted following an initial inventory, with the same required information as in the initial inventory.**

- a. True
- b. False

Answer: a. True. A biennial inventory is conducted following an initial inventory, with the same required information as in the initial inventory; this includes an actual count for all Schedule II controlled substances, and an estimated count for Schedule III–V controlled substances unless the container holds more than 1,000 dosage units and the container has been opened.

7. **Inventory of Schedule II controlled substances surrendered for disposal require the utilization of DEA Form 41.**

- a. True
- b. False

Answer: a. True. DEA Form 41 Registrants Inventory of Drugs Surrendered “is the appropriate form to utilize when surrendering Schedule II controlled substances for disposal.”

8. **Name two programs that would assist a pharmacist in proper oversight in the utilization of controlled substances.**

Answer: A medication-use evaluation program and a surveillance program.

9. **Name three factors that have been responsible for the increased scrutiny of controlled substances in a hospital environment.**

Answer: Federal and state laws, patient safety, and complexity of pharmacotherapy.

10. **Name three key requirements for the effective management of controlled substances.**

Answer: Appropriate inventory and record requirements, appropriate physical and storage requirements, and appropriate policy and procedures in the management of controlled substances.

CHAPTER DISCUSSION QUESTIONS

- 1. Discuss the key aspects of a medication-use system that are vital to the management of controlled substances within healthcare systems.
- 2. Discuss factors that influence the need for pharmacist involvement in controlled substances management.
- 3. Discuss criteria that pharmacists should consider when adding any controlled substances to the formulary.
- 4. Compare and contrast physical security and storage requirements for controlled substances versus noncontrolled substances.
- 5. Compare and contrast the pharmacist involvement in the handling of controlled substances during the ordering and dispensing process in an institutional environment versus retail (outpatient) environment.

CHAPTER 9

Informatics

Bruce W. Chaffee



LEARNING OBJECTIVES

After completing this chapter, readers should be able to:

1. Define pharmacy informatics and other key terminology.
2. Contrast the terms data, information, and knowledge.
3. Describe the operational, clinical, and administrative applications of informatics.
4. Explain how pharmacists can protect the confidentiality of medical information.
5. Discuss the roles, responsibilities, and necessary training of a clinical informatics pharmacist.



KEY TERMS AND DEFINITIONS

- **Authentication:** A method of identifying a user, typically by having the user enter a valid user name and password, before program access is granted. The process of authentication is based on each user having a unique set of criteria for gaining access. It provides protection against unauthorized access or forgeries and is a dimension of information security.
- **Bar-coded medication administration (BCMA):** An information technology solution that links an electronic medication administration record (eMAR) with bar-coded item-specific identification and the bar-coded patient

identifier, which enables the healthcare provider to administer medications with general confirmation of the five rights of medication administration: right patient, right dose, right route, right time, and right medication. Use of the system at the bedside provides more precise patient and medication information resulting in improved accuracy and reduced medication errors.

- **Biometrics:** Technologies that measure and analyze human body characteristics such as fingerprints, eye retinas and irises, voice patterns, facial patterns, and hand measurements, for authentication purposes.
- **Clinical data repository (CDR):** A real-time database that consolidates data from various sources to present a unified view of a single patient's clinical information. A CDR is generally constructed for transactional use of data.
- **Clinical decision support (CDS):** Components of information systems that are designed, configured, or programmed to (1) minimize the likelihood of user error and/or (2) use diagnosis, treatment, laboratory, and other information to assist prescribers and other health professionals with decision-making tasks to support the clinical care of patients. CDS may be asynchronous (separate from the order entry process) or synchronous (at the time of order entry).
- **CDS alert:** The specific action dictated by a CDS rule. For example, an alert may appear as a pop-up notification window within a computerized provider order entry application, a

page sent to a recipient via the system application, or a flag appearing on a patient summary view.

- **CDS rule:** A specific clinical decision support instruction that uses encoded health knowledge in conjunction with an event monitor to dictate that, when a certain set of circumstances is present, a specific action is initiated. For example, a CDS rule might monitor patients on gentamicin therapy and be programmed to fire an alert to a pharmacist if a patient experiences a 0.5 mg/dL increase in serum creatinine concentration.
- **Computerized provider order entry (CPOE):** A component of an electronic medical or health record that enables providers to enter patient care orders for use by order receiving departments such as pharmacy, laboratory, or radiology.
- **Confidentiality:** The state of ensuring that information is accessible only to those authorized to have access.
- **Data:** Pieces of information that represent the qualitative or quantitative attributes of a variable or set of variables. Data are typically the results of measurements and are often viewed as the lowest level of abstraction from which information and knowledge are derived.
- **Data warehouse:** An extract or copy of patient level data contained in one or more application databases for the purposes of data extraction via reports and queries.
- **De-identification:** The removal of identifying information (i.e., patient name, medical record number, birth date, social security number) from medical records to protect patient privacy.
- **Electronic health record (EHR):** A comprehensive electronic medical record for a patient that extends beyond a single office, clinic, hospital, or health system. EHRs are accessible by all authorized clinicians across environments of care including physician offices, emergency departments, urgent care facilities, hospitals, and long-term care facilities.
- **Electronic medical record (EMR):** A digital collection of data about a patient from one clinician office, clinic, hospital, or health system. EMRs contain orders, notes, results, and demographic information about patients.
- **Encryption:** Encryption is the conversion of data into a form, called a *ciphertext*, which cannot be easily understood by unauthorized people. Encryption is especially important in wireless communications, but it is also a good idea when carrying out any kind of sensitive transaction to prevent unauthorized access to information.
- **Informatics:** The intersection of the science of information (information, computer, cognitive, and/or organizational sciences) with a specific area or domain of professional practice that uses or engineers technology or processes information.
- **Information:** Data with relevance or purpose. Information has meaning; for example, the user has knowledge of the context of reported data.
- **Information security:** The state of protecting information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction. It is often described by the concepts of confidentiality, privacy, integrity, nonrepudiation, authenticity/trustworthiness, availability, accountability, and auditability.
- **Interface:** A means of transmitting and translating information between entities, which do not speak the same language, such as between a human and a computer (a user interface) or between two computer systems (software interface).
- **Intranet:** A private computer network that uses Internet technologies to securely share any part of an organization's information or operational systems with its employees.
- **Knowledge:** Expertise and skills acquired by a person through experience or education; the theoretical or practical understanding of a subject.

- **Medication administration record (MAR):** A report that serves as a legal record of the drugs that a nurse or other healthcare professional administers to a patient at a facility. When present electronically, this is often referred to as the eMAR.
- **Nonrepudiation:** The concept of ensuring that a party cannot repudiate, or refute the validity of a statement or information. On the Internet, a digital signature is used not only to ensure that a message or document has been electronically signed by the person who purported to sign the document, but also to ensure that a person cannot later deny furnishing the signature since a digital signature can be created only by one person.
- **Patient management system:** A system that stores information about a patient such as his or her name, unique identifying medical record number, contact information, and date of birth. A patient management system may also serve as the patient's admission, discharge, and transfer (ADT) system that tracks dates and locations of appointments and movement within the health system.
- **Pharmacy informatics:** The application of information sciences to pharmacy practice and the medication-use process.
- **Pharmacy information system (PIS):** Complex computer systems that have been designed to meet the needs of a pharmacy department.
- **Point-of-care devices:** Devices used in the delivery of healthcare such that they are utilized within the care process at the specific time in which the information is needed or collected.
- **Radiofrequency identification (RFID):** The use of an object (typically referred to as an RFID tag) applied to or incorporated into a product or person identifier (wrist band) for the purpose of identification and tracking using radio waves.
- **Verified Internet Pharmacy Practice Sites (VIPPS):** Created in 1999 by the National Association of Boards of Pharmacy (NABP), the Verified Internet Pharmacy Practice Sites (VIPPS) accreditation program provides a means for the public to distinguish between legitimate and illegitimate online drug sellers. The VIPPS program and its seal of approval assure the public that VIPPS retailers are legitimate online pharmacies appropriately licensed in each state to which they ship pharmaceuticals.
- **VeriSign™:** A provider of Internet infrastructure services that allows companies and consumers to engage in trusted communications and commerce by providing encryption and authentication services.



INTRODUCTION

This chapter focuses on **informatics**, specifically **pharmacy informatics**, by exploring several topics that are pertinent to pharmacists working in healthcare systems. A basic overview of data and data management is provided including a description of sources of information available to pharmacists, how clinical data are stored, and how data are transferred between systems for use by clinicians. The applications of various information and automation technologies are discussed for the following areas of pharmacy practice: operations/drug distribution, clinical, administration, and workflow and process improvement. More specific topics, such as clinical decision support and information security and confidentiality, are reviewed later in the chapter. The chapter concludes with a discussion of the role of the clinical informatics pharmacist, including opportunities and training for those interested in the field of pharmacy informatics as well as the future direction for the pharmacy informatics field.

The term *informatics* has been defined many different ways in many different forums. One definition, derived from an online source that is no longer accessible, described informatics as “the application of computer and information sciences to the management and processing of data, information, and knowledge.”¹ A broader definition might describe informatics as the science concerned with the gathering, manipulation, classification, storage, retrieval, and dissemination of recorded knowledge. This broader definition incorporates several key concepts that relate to data and data management that are important for understanding technology’s role in optimizing patient care outcomes and are discussed later in this chapter. The use of health information technologies, as part of the daily activities of healthcare professionals, also has an expanded, colloquial meaning—the techniques and practices used to manage and operate information systems and technology.

On the surface, these definitions of informatics might seem quite different, but they are interrelated and reflect the evolution of what has often been an abstract term. A thoughtful essay by Friedman offered three models of what informatics “is” contrasted with activities that describe what informatics “isn’t.” One of these models, similar to understanding the definition of clinical sciences, is helpful in simplifying the discussion for this chapter—informatics can be considered the intersection of relevant basic informational sciences (information, computer, cognitive, organizational) with a specific area, or domain, of professional practice.²

In healthcare, informatics can be divided into domains, typically derived by profession or specialty area, such as medical informatics, pharmacy (or medication) informatics, nursing informatics, biomedical informatics, public health informatics, and other areas. For example, medical informatics might apply to aspects supporting medical research, physician education, and diagnosing patients; pharmacy informatics might be focused on areas involving the medication management system within the healthcare environment.³ Other informatics domains might focus on processes and systems specific to those specialties or domains. Despite nomenclature that distinguishes these domains, there can be substantial overlap between the various aspects of informatics each domain may claim (**Figure 9-1**).⁴ For example, both nursing and pharmacy may have interests in the technologies, operational workflow, and data related to bar-code medication administration, but only phar-

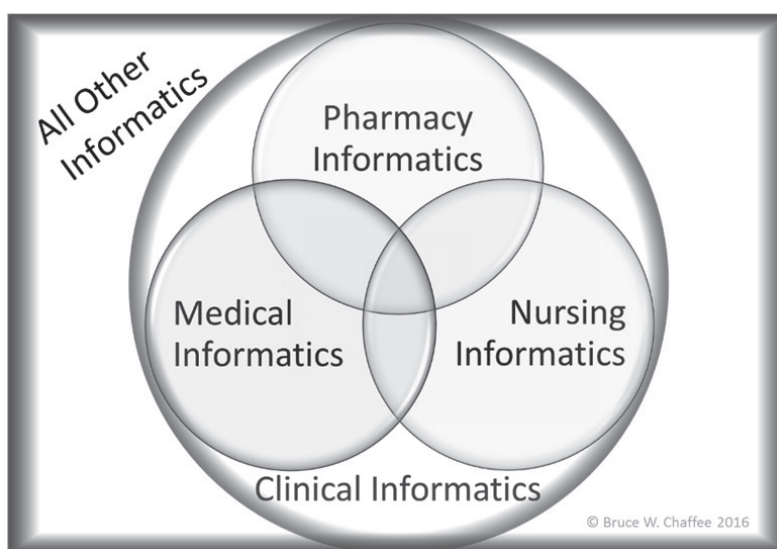


FIGURE 9-1. Example relationships between informatics domains.

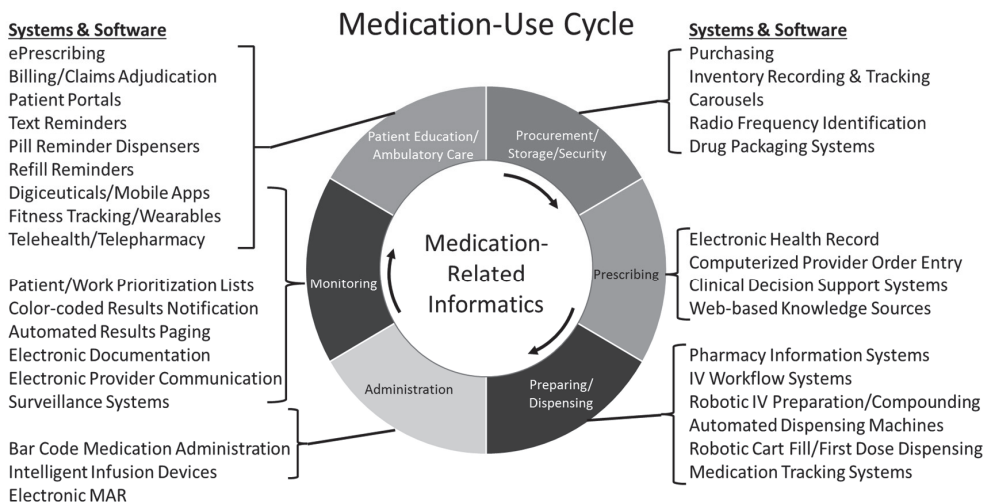
macy may have interest in accurate billing and only nursing may have interest in their staff's performance related to medication documentation.

Figure 9-2 shows the range of technologies that might be included in the broader definition of pharmacy informatics.⁴ The technologies included in this figure have grown dramatically since the passage of the U.S. Health Information Technology for Economic and Clinical Health (HITECH) Act, a part of the 2009 American Recovery and Reinvestment Act. HITECH stipulated that physicians and hospitals transition from paper-based systems to **electronic medical record (EMR)** systems (note the important difference between an EMR versus an **electronic health record [EHR]**). Other societal drivers that continue to spur the development of new technologies include:

- Policies, driven by the move toward the provision of affordable care for more Americans and the need to include quality as a factor in health-system reimbursement models.
- The emergence of accountable care organizations and patient-centered medical homes, developed to provide higher quality, more coordinated care across the provider continuum.
- The increased need for ensuring the security, integrity, and provenance of the drug supply chain.

Some of these technologies will be discussed in this chapter, but a more complete picture can be provided by reading Chapters 10 and 11 on electronic data management and automation in practice.

Many different computing devices are used in healthcare environments. Behind the scenes, large computer servers run advanced operating systems with multiple processors to power many of the software applications used in the care of patients. More visible to clinicians, a variety of devices are used by healthcare providers including personal desktop computers, laptops, tablets, personal digital assistants (PDAs), and cell phones. In fact, most healthcare devices incorporate some form of informatics.



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FIGURE 9-2. Technologies associated with pharmacy informatics.

IV: intravenous; MAR: medication administration record

Today, information technology is increasingly integrated into the entire medication management cycle from procurement through ambulatory care. This includes product procurement and storage, prescriber order entry, integration with pharmacy systems and dispensing devices, electronic documentation of medication administration, and prioritization and documentation of pharmacists' clinical patient care activities. Health systems have rapidly adopted these technologies to improve patient safety, reduce errors, and improve the efficiency of care processes.

Pharmacy informatics continues to be a broadly scoped field that is rapidly growing. Looking ahead, pharmacists will continue to use informatics to provide care for patients in inpatient and ambulatory environments. The widespread use of electronic prescribing has allowed pharmacists even more opportunity to focus on the appropriateness and safety of medication therapy for patients rather than the mechanics of drug distribution.

DATA, INFORMATION, AND KNOWLEDGE MANAGEMENT

To understand informatics, one must understand the differences among data, information, and knowledge.⁵ **Data** are simply discrete and objective facts about a subject or an event. Good examples in healthcare are patient laboratory values, drug orders for a patient, or the patient's weight. Data are easy to capture and store in media such as databases and files.

Information is often defined as data that have relevance and purpose. Information has meaning whereas pure data do not because information is contextualized, categorized, calculated, corrected, or condensed (**Figure 9-3**). In healthcare, an example of information is knowing that a particular laboratory result was high or low based on documented reference values. We understand the result (data), the basic *context* (when and why it was drawn), its *category* (the name of the drug sampled, the numeric laboratory value, and units of measure), how to *calculate* it (analyze it relative to its reference range and prior results), if it needs *correction* (its accuracy based on the value relative to sampling time, site, etc.), and if we can *condense* it (graph it to better summarize trends).

Knowledge is broader, deeper, and richer than data and information. Knowledge is combining information with framed experiences, norms, and contextual understanding. Information is transformed into knowledge through *comparison* between the current situation and another similar one, understanding the *consequences* of the information, knowing how the information *connects* to other information, or understanding what people think about the information through *conversation*. Knowledge is very difficult to capture as it often resides in people's heads. In healthcare, having knowledge means that a clinician knows the consequences of a particular laboratory test or knows whether the drug therapy prescribed for a patient is adequate to treat the condition being treated. Knowledge is often transferred tacitly through teaching, one-on-one interactions, experience, and practice norms.

Why is this important in the field of informatics? Informatics focuses on the use of technology to improve the use of data, information, and knowledge. Tools

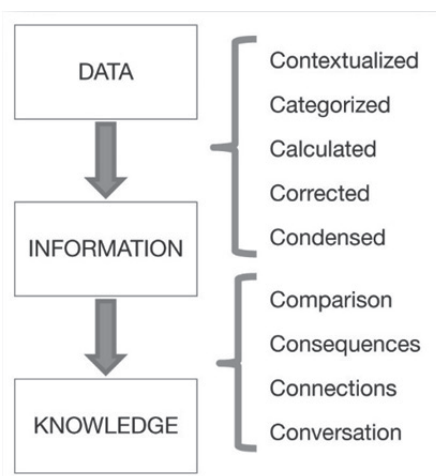


FIGURE 9-3. Relationship of data, information, and knowledge.

and technologies used to improve these areas vary considerably in their features and functions depending on whether the focus is on data storage, retrieval and transfer, information gathering and sharing, or knowledge sharing. Understanding the differences helps the informatics pharmacist best utilize tools and technologies to solve the business problem at hand.

Accessing Sources of Information and Knowledge Content

Historically, pharmacists have used hard-copy, printed references to access drug information, and other knowledge resources. However, today's pharmacists are increasingly utilizing electronic information sources. The advantages of electronic information include availability of information from almost anywhere within the healthcare system and at the point of service (especially with the availability of wireless networks and mobile devices), reduced space requirements for storing information, greater ability to maintain up-to-date information, and significantly improved efficiency of information retrieval. Many pharmacy and provider order entry systems can embed web-based links to enable direct access to the same content from these software applications without requiring the user to open a second software program, saving time and reducing system complexity. This increased availability of information should lead to better decision making and improvements in the quality of care provided.

A wide variety of information retrieval and knowledge sources are currently available. The Internet has emerged as a major source that lay people and healthcare professionals use alike. According to the Pew Institute, 72% of Internet users sought healthcare information online last year and more than three out of four users began their search using one of the common Internet search engines.⁶ In 2002, it was estimated that more than 100,000 websites provided health information.⁷ Although this estimate has not been tracked over time, it is likely that this number has grown exponentially.

A list of the most popular Internet websites for healthcare information is shown in **Table 9-1**.⁸ There are a few resources available to narrow down the plethora of websites to those with higher reliability and accuracy. One consumer-oriented site offers a list of the top 100 health websites you can trust based on the following criteria: credibility, sponsorship/authorship, content, audience, currency, disclosure, purpose, links, design, interactivity, and disclaimers.⁹ Given the scope of offerings on the Internet, the concept of *caveat emptor* ("let the buyer beware") should be followed by consumers and healthcare providers alike when obtaining information from Internet sources.

It is important for healthcare professionals to understand that patients are increasingly seeking information for themselves, friends, and family members from Internet sources that may or may not be vetted as legitimately containing accurate information. Pharmacists should discuss the source and validity of information offered by patients as part of the care they provide to patients. The same consideration needs to be made when information is discussed among healthcare professionals. This concept of source and information validity further highlights the difference between the definitions of *information*

KEY POINT . . .

To understand informatics, one must understand the differences among data, information, and knowledge.

. . . SO WHAT?

When dealing with informatics, it is easy to drown in the vast amounts of available data and information. Data are just meaningless facts if they are not put into some useful context. And information is useless unless the recipient has the knowledge to make proper decisions.

TABLE 9-1.
The 15 Most Popular Health Websites (January 2016)

1. WebMD.com	9. Healthline.com
2. NIH.gov	10. Mercola.com
3. Yahoo.com/health	11. Health.com
4. MayoClinic.com	12. MindBodyGreen.com
5. MedicineNet.com	13. Medscape.com
6. Drugs.com	14. RxList.com
7. EverydayHealth.com	15. MedicalNewsToday.com
8. HealthGrades.com	

For more information, see reference 9.

and *knowledge*. Patients may have information about a drug or disease, but they may not have the benefit of framed experiences and context when making decisions about their healthcare options.

Although it is not feasible to list all of the sources of trustworthy electronic health-care information, some frequently used sources of information available to healthcare professionals are listed in **Table 9-2**. The easy and convenient access to the literature, drug information databases, and online continuing education help pharmacists (even in remote areas) enhance and maintain their professional knowledge to assist in their practice.

The next (several) generations of knowledge systems will likely be “smarter” and include the availability to create customized decision support logic to improve patient care. That is, when a question is asked about a drug, the capability will exist of providing information within the context of the patient or clinical scenario as well. This enhancement will allow the knowledge source to return information that is specific to that particular patient or clinical situation. For example, instead of reporting the usual dosage range of a particular drug, the information provided might be a dosage recommendation specific to *this* patient with a given age and creatinine clearance. As these knowledge systems mature, other factors such as diagnosis, genetic profiles, and a patient’s history with a given medication will likely be considered.

One clear impact of the Internet is that patients will be more educated and have greater access to information than ever before. Thus, patients will be better prepared and engaged but also potentially misinformed about their conditions and medications. To help patients wade through the vast quantities of the information available on the Internet, pharmacists and other healthcare providers need to be not only clinically knowledgeable, but also cognizant of the steps needed to obtain reliable information. Some health systems are providing patients with a list of endorsed, reliable health information links to assist them in their self-education.¹⁰ Criteria that can be used to evaluate the quality of health-related websites are listed in **Table 9-3**.⁷

The EMR, Clinical Data Repositories, and Data Warehouses

In addition to the availability of commercial clinical knowledge content, the need arises to access locally stored, clinical data about the patient for use in the context of patient care. Most software applications maintain a repository of patient-specific clinical data, but these are often located in individual departments that are not accessible to all providers for functional, practical, and security reasons. Rather than make many system-to-system database **interfaces** and create multiple, redundant repositories of these data in ancillary system

TABLE 9-2.**Information Retrieval/Knowledge Sources**

- Electronic drug information/drug database resources (e.g., Micromedex®, Multum®, ePocrates®, Lexi-comp®, Medi-Span®, Facts & Comparisons®, Gold Standard®)
- Electronic databases and search engines (e.g., Medline®, International Pharmaceutical Abstracts®, PubMed®)
- Electronic journals
- Electronic textbooks
- Natural Medicines Comprehensive Database

TABLE 9-3.**Important Quality Criteria for Health-Related Websites**

- Transparency and honesty
- Transparency of provider of site, purpose, and objective of site
- Clearly defined target audience
- Transparency of all sources of funding
- Authority
- Clear statement of sources for all information and date of publication
- Privacy and data protection policies
- Clear and regular updating of information with date clearly displayed
- Accountability for information
- Process for user feedback and appropriate oversight responsibility
- Editorial policy has clear statement on process used for selection of content
- Guidelines on accessibility, searchability, and readability

Source: Commission of the European Communities. *J Med Internet Res.* 2002; 4(3):e15. <http://www.jmir.org/2002/3/e15>.

databases (where feasible), many institutions choose to collect data maintained in several software applications and transmit it to tables contained in a larger database for clinical use. This collection is often referred to as a **clinical data repository (CDR)**.¹¹

The EMR's database contains the largest amount of clinical data and typically has additional storage tables for ancillary data, so many institutions use the EMR database as their CDR. Data are imported into the EMR from ancillary systems, typically via interfaces. If the interface is bidirectional, clinical information can be extracted from the EMR when necessary for use by ancillary departments. Reports can be generated out of the EMR, but the structure of an EMR database may not be conducive to efficient reporting. Moreover, the volume and complexity of reports could negatively affect the EMR performance, slowing transactions such as order entry and documentation. One solution for this problem is to create a separate database for report extraction. This redundant database is a "mirror" or copy of the production database used by the EMR. This copy, often called a **data warehouse**, may contain an archive that can be minutes to many hours old, but it contains the same data as are available in the production database as of the time designated by the archiving schedule. Data warehouse tables are generally structured for efficient retrieval of data from report queries in contrast to EMR databases, which are structured for efficient clinician workflow.¹¹ The important point is that institutions need central sources of valid clinical data for their patient care and information needs, generally addressed by a clinical data repository and a data warehouse, respectively.

SYSTEMS INTEGRATION AND INTERFACING

The complexity of healthcare information systems requires that a number of interfaces be present to leverage the information stored in multiple systems and to better integrate care. Software interfaces allow patient information to flow directly into these technologies from a **patient management system** without the need for pharmacy staff to reenter the data by hand. Interfaces to laboratory systems allow easy retrieval of patient laboratory results, and rules can be programmed in the systems to promote safe and effective use of drugs. In addition, interfaces to external devices such as intravenous (IV) compounders, automatic dispensing cabinets, and robots increase the efficiency of the overall pharmacy operations.

Pharmacist-Computer Interactions

Many different types of software are used in healthcare informatics, and pharmacists have varying ways in which they work with software. Software can be a simple, unchangeable system program solely designed to operate a piece of equipment or medical device, or it can be a complex application designed for data entry, storage, exchange, and retrieval. Most pharmacists generally do not get involved in software programming, especially for the complex applications required in today's healthcare environment. The primary interaction hospital pharmacists have with software is directing the software to perform various tasks via the user interface on the display screen of the computer or device. This interaction can consist of activities such as programming infusion rates, entering orders, entering compounding volumes, or extracting reports from equipment, devices, and systems such as the **pharmacy information system (PIS)** or EMR.

Beyond this day-to-day interaction with the user interface, pharmacists and other healthcare professionals can get more involved in the intricacies of an information system by working with system analysts or by directly working with the system. Pharmacists in these roles are responsible for defining the business logic required for configuring a system to meet workflow needs and/or policies using the system's software configuration options. These activities require computer skills generally acquired through specialized training and experience obtained by working with the various automation and information systems.

KEY POINT . . .

The primary interaction hospital pharmacists have with software is directing the software to perform various tasks via the user interface on the display screen of the computer or device.

. . . SO WHAT?

To utilize computer software, practicing pharmacists do not need to know how to program computers using complex machine language. They just need a user interface on some computer or device. The real value that informatics pharmacists provide is the value gained by combining the pharmacist's clinical expertise and knowledge of the medication-use system with their knowledge of information technology. Informatics pharmacists are specially trained to direct or make system design changes.

Access to and Use of Information

One of the most important aspects of any information system is the benefit it provides an organization in terms of accurate and efficient information storage and retrieval. Modern software applications contain three tiers: the *client tier*, which is where the user interacts with the system; the *application tier*, which is the software stored on the local machine; and a *database tier*, which contains the database tables where information is stored as a result

of user input into the application's user interface. Depending on the complexity of the application, tens of thousands of discrete data elements may be stored in the application's database management system, including patient-level data (e.g., dispensing, billing, facility, audit information).

Although most information retrieval is conducted from within the application, some is conducted externally for functionalities other than those originally intended from the system. For example, data in a PIS (or the pharmacy subsystem of an EMR) contain useful historical utilization information about commonly used drugs, dose forms, doses, and frequencies of administration that can be helpful when making informed decisions about drug-use policies within an organization. That data may be retrieved using a vendor-supplied report writer application within the system or a query using external report writing software that connects to the PIS/EMR database.

A second manner in which data contained in an information system may be useful beyond its original intent is when data need to be imported from, exported to, or exchanged with another information system. A few of the many situations where this may occur include (1) input of patient-specific status and location data acquired from a patient management system (e.g., patient admission, discharge, transfer information), (2) importation of laboratory information into the EMR for the purposes of supplying healthcare providers with important clinical data for use in context with medication orders, (3) provision of pharmacy medication-use information to the hospital financial system for the purposes of billing, and (4) the clinical integration between an outpatient PIS and the EMR system to ensure accurate and complete medication profile information.

Using Information Systems to Increase Work Efficiency

One of the most widely used information systems for pharmacists is the inpatient PIS, whether it be a standalone system or a pharmacy-centric subsystem within an EMR. For the purposes of this discussion, the inpatient PIS is considered to be either of these systems. The inpatient PIS serves as the backbone for pharmacy work activities. The PIS automates and organizes the daily dispensing workflow for pharmacy staff while also structuring many of the pharmacists' clinical activities. Printed cart fill lists and IV medication labels can be generated from the PIS database allowing the pharmacy department to sort and perform work activities in batches based on patient location, type of medication, anticipated administration time, and/or other sorting features.

In institutions without a comprehensive EMR, the PIS can also be used to facilitate the work of other healthcare providers. For example, the PIS can be used to print paper **medication administration records (MARs)** to help nurses organize and document activities related to the medication administration process. MARs provide nurses with sufficient information to safely and accurately administer medications to patients according to the prescriber's desired time schedule, along with a method to indicate that medication administration occurred or did not occur.

More globally, EMRs can be used to organize work activities for pharmacists and other healthcare providers. Most contemporary EMRs contain patient lists, patient profiles, demographic information, patient care notes, order forms, and other features that can be used to organize work. Orders written using **computerized provider order entry (CPOE)** within an EMR can generate electronic or printed work lists or tasks for a wide variety of departments or individual healthcare providers. Order information from the CPOE system combined with product information within the PIS can be used to create an electronic work or task list for documenting medication administration. Not surprisingly, this is called an eMAR and it has replaced printed paper MARs. The advantages of eMARs include:

- Providing the ability to access the chart at multiple locations
- Ensuring providers have access to the same information in real-time
- Offering a more readily available system for staff (individually or in aggregate) to audit medication administration performance
- Facilitating billing based on actual drug administration

The pharmacy department is the recipient of a large proportion of physician orders. The format for receipt of these orders can be quite different from one hospital to another depending on a number of factors. These factors include work flow patterns, extent of technology deployment, physical size and layout of the hospital, type of facility, and practice base of the physician (e.g., independent practice, group practice, hospitalist, resident). Pharmacy orders can be (1) handwritten or electronic; (2) individual or grouped (e.g., single sheet of paper or order set); (3) entered by physicians or a physician agent (e.g., nurse, clerk); or (4) delivered manually via facsimile machine, via document imaging technology, or electronically from the EMR system to the PIS. Once orders are received in the pharmacy, it is the pharmacist's responsibility to ensure the orders are reviewed for appropriateness of therapy and accurately recorded in the patient's electronic profile in the PIS. In general, computer prescribed orders delivered to the pharmacy via a dedicated orders printer or an electronic interface to a PIS are more likely to be legible, complete, and delivered in a timely manner when compared to handwritten orders.

Electronic Interfaces

Several options are available for handling medication orders that are electronically delivered to the pharmacy department. The first, and preferred option, is to receive orders as part of an integrated EMR. This has quickly become the standard of practice for inpatient orders, assuming the EMR's pharmacy subsystem functionality meets the departmental workflow needs. Other options are for the pharmacist to take printed copies of the order and reenter the orders into the PIS, to transmit orders electronically from a EMR system to the PIS via a one-way interface, or to transmit orders back and forth between systems using a bi-directional orders interface (**Figure 9-4**).¹² Electronic transmission saves

KEY POINT . . .

The PIS often serves as the backbone for pharmacy work activities.

. . . SO WHAT?

To understand the work of the pharmacy and the interrelationships between its various tasks, one needs to understand the functionality of the PIS and how it fits within the workflow of the pharmacy department.

KEY POINT . . .

The best integration option for a PIS is to receive medication orders as part of an integrated EMR. With interfaces, the overall strength of the integration between the EMR system, the PIS, and the interface is only as robust as the weakest component.

. . . SO WHAT?

In informatics, everything is connected. This interconnectedness is both a strength and weakness. The strength lies in quick access to needed information. The weakness lies in the weakest component of the system's ability to reduce the performance of other parts of the system. For example, if one system is down, then the entire workflow needs to change in order to adjust for the missing component.

time and prevents transcription errors (wrong patient selection, omitted orders, mistaken entry of information) that can occur with reentry of orders from paper copies. The primary disadvantage of the interfaced transmission of orders is the complexity—every component must work and work well in conjunction with each other. For example, transmission failure can result due to breakdowns in software or hardware components in the EMR system, the PIS, or the interface itself. Indeed, the overall strength of the integration is only as robust as the weakest component. A breakdown can result in significant system downtime, workflow changes, and order reconciliation challenges; thus, elaborate downtime procedures are required to ensure that errors do not occur.

PRACTICE APPLICATIONS OF INFORMATICS

Pharmacy has been at the forefront of using technology to improve medication use for many decades. These improvements have occurred at each of the medication-use cycle stages, which include procurement and storage, prescribing, preparation and dispensing, administration, monitoring, and the patient education/ambulatory use of medications. Initially, PISs were developed primarily to ensure proper billing occurred and to assist in improving the efficiency of drug distribution through the creation of dispensing lists and production of IV medication labels.¹² As medical care became more complex and clinical pharmacy practice models grew and evolved, applications and technologies were added and enhanced to provide additional efficiencies and safety surrounding pharmacy operations, clinical pharmacy practice, pharmacy administrative activities, and for other disciplines.

Operational/Drug Distribution

Informatics plays many varied and significant roles in the daily operation of health-system pharmacies. The purchasing process is enhanced through the use of electronic ordering from wholesalers and pharmaceutical companies. Transactions conducted through these

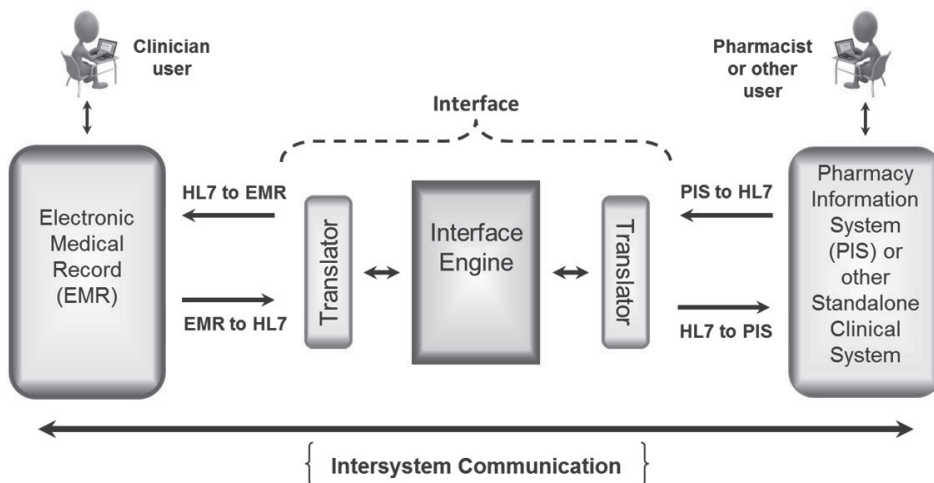


FIGURE 9-4. Possible interfaces between an EMR and pharmacy information system (PIS) or other system. HL-7 indicates that the communication standards between electronic information systems are compliant with the standards set by the Health Level 7 organization, which are designed meet communication needs within a healthcare setting.

Source: Originally published in Chaffee BW, Bonasso J. Strategies for pharmacy integration and pharmacy information system interfaces, part 2: scope of work and technical aspects of interfaces. *Am J Health-Syst Pharm.* 2004; 61(5):506-14. ©2004. American Society of Health-System Pharmacists, Inc. All rights reserved. Adapted with permission.

systems help pharmacies track the quantities and costs of medications obtained and ensure accurate receipt of the ordered items. Medication storage and security have been improved through the use of carousels, which incorporate both the efficient physical storage of medications and electronic storage of medication distribution transactions for security and tracking purposes.

Computerized patient medication profiles, either as a standalone PIS or as part of an EMR system, significantly improve the efficiency and safety of the medication-use system by reducing human-induced legibility, transcription, and dispensing errors while eliminating the physical delivery of paper orders.¹² Medication profile records, which include drug histories, also allow pharmacists to better manage drug therapy, thus improving the quality of patient care. As mentioned earlier, the PIS, or pharmacy subsystem of a comprehensive EMR, facilitate efficient operations through automated label generation, patient billing, batch processing of work activities, and other distributive tasks that can help free pharmacists' time to provide better pharmaceutical care.

Technologies have advanced to include enhanced safety and information management during the compounding and/or dispensing processes of medication preparation, including the use of **point-of-care devices** such as automated dispensing cabinets, IV compounding and workflow management systems, and inventory management and medication tracking systems for pharmaceuticals. Some of these systems are integrated within larger EMR systems, but these systems can also be standalone ones containing richer functionality than larger EMR systems offer.

Clinical

Informatics is increasingly playing a role in clinical pharmacy activities. Automation has permitted pharmacists to transition work for historically important professional functions such as dispensing, to robots, automated dispensing cabinets, and compounding devices. As a result, pharmacists are better able to apply their knowledge to patient-specific clinical issues. Pharmacists, in part due to technology improvements, can participate more effectively in patient care teams and use their clinical skills to optimize medication use and improve patient care.

A key area of growth has been improving a pharmacist's access to information about the patient and his or her care. Technology helps pharmacists collect data, filter results, provide decision support, and record pharmacist activities. Most EMR systems contain all of the patient's orders and results, whether they are from the pharmacy, laboratory, radiology, or some other department. Functionality in EMR systems allow end users to filter and sort lists to specific order items, locations, departments, or medical services, streamlining the work of clinicians. Many clinical applications, including EMRs, are available for use in mobile devices such as PDAs, tablet PCs, and even cell phones.

Another important area is documentation of clinical pharmacy activities. Initial efforts to document pharmacists' interventions involved the use of paper forms and handwritten notes.¹³⁻¹⁵ Paper documentation was cumbersome and time-consuming; the handwritten forms had the potential to be lost or unreadable and were difficult to compile.^{14,15} Now technology facilitates documentation of pharmacists' interventions and patient care activities.^{14,16,17} Early versions of these systems required pharmacists to record their interventions on paper and later enter them into the computer—a process that did not completely eliminate the drawbacks of manual documentation but made data interpretation more efficient.¹⁶ The better systems, however, utilize software interfaces that allow pharmacists to document their work directly into hand-held mobile devices. Popular with professionals, these mobile devices provide real-time or synchronized connections to the healthcare information systems. Additional advantages include reduced time needed for documentation and improved ease of use, accessibility, efficiency, and general acceptance.¹⁷

Contemporary documentation systems allow pharmacists to not only receive important clinical care alerts (discussed later under the Clinical Decision Support section) but also enable them to document their actions via pharmacy notes.¹⁸ These notes enable pharmacists to communicate with one another about the need for additional follow-up for specific patient care issues, such as checking laboratory values or monitoring for adverse events. Although these systems are currently very helpful to pharmacists, future advancements such as the creation of a ranking or scoring prioritization system will prove even more beneficial as the demands on pharmacists' time grows.^{19,20}

Administrative

The management of pharmacy services has improved greatly through technology and informatics. Managers have information tools that allow them to better assign resources to meet workload requirements, identify opportunities for cost savings, and justify new services. Medication system automation tools have allowed managers to move pharmacists into clinical roles and increase the overall safety of the medication-use system. A number of administrative applications of informatics are listed in **Table 9-4**. Data required for these reports can be obtained by accessing the data contained in each system's database or via the data warehouse. Aggregation of these data into business intelligence software enables managers to create specific dashboards to describe departmental performance and identify opportunities for further improvement.²¹⁻²⁵

Workflow and Process Improvement

Workflow and process improvement can also be attained through improved knowledge sharing. Technology, including email and the web, has made sharing knowledge much easier and at a reduced cost. Internal websites, part of the institutional **intranet**, can be used to provide clinicians with quick access to information through local and national clinical guidelines, disease management strategies, drug formularies, and other content.

TABLE 9-4.

Administrative Uses of Informatics

Item	Benefit
Drug usage reporting	<ul style="list-style-type: none"> ■ Compliance with policies and standard practices ■ Medication-use evaluation and quality improvement ■ Drug cost tracking and control
Workload reporting	<ul style="list-style-type: none"> ■ Measurement of efficiency and productivity of processes
Inventory management systems	<ul style="list-style-type: none"> ■ Control of inventory costs and turns ■ Monitoring of purchasing activities ■ Management of recalls and drug shortages ■ Monitoring of compliance with regulatory requirements for controlled substances
Scheduling systems	<ul style="list-style-type: none"> ■ Management of employee schedules ■ Management of personnel costs
Portals	<ul style="list-style-type: none"> ■ Remote monitoring and exchange of information ■ Creation of knowledge sources regarding drug therapy ■ Patient access to medical records and communication with providers

Perhaps the most important improvement seen with technology and automation is increased safety. Technologies such as bar-code verification of medications have helped ensure that the five rights of medication administration are met—the *right drug* is available to the *right patient* in the *right dose* and *right route* of administration at the *right time*. Drug inventory and stocking are confirmed by scanning bar codes for the drug and the bin where the drug is stored; bar-code IV workflow and verification systems ensure that the correct products are selected for compounded and dispensed IV products; and bedside **bar-coded medication administration (BCMA)** ensures that the correct drug (product, dose, and dose form) is being administered according to the patient’s medication profile and schedule for administration. **Radiofrequency identification (RFID)** chips may be deployed in the future as technology that can identify products, track their movements, and enable linking of information with purchasing and inventory control systems. These technologies can provide security to prevent theft and other loss, help assure pharmacy staff of the provenance of the medications used in the supply chain, and ensure that drugs are maintained within appropriate temperature ranges. Future advances in technology and information systems will continue to help health systems improve the safety and quality of the medication-use system.

CLINICAL DECISION SUPPORT

The term **clinical decision support (CDS)** represents the features and functions of an information system that passively or actively convey clinical knowledge content to health-care professionals so that choices can be made in the best interest of patient care. There are many methods for providing system users with clinical knowledge. *Passive* conveyance of clinical knowledge content occurs as a result of system design features and choices made during system configuration that may not necessarily be apparent to the user of the system.^{26,27} An example of passive methods for providing basic CDS is the use of structured data elements for medication ordering in a PIS or EMR system (**Table 9-5**). During system configuration, tables are built for each drug entity that define the allowable drug order choices system users can select during order entry. Many systems will allow the institution to determine the appearance and order of the selections and even provide default selections. By limiting the choices a prescriber can make, the institution can help prevent the errors that occur from ordering medication doses, routes of administration, or frequencies that are unsafe, subtherapeutic, excessively costly, nonstandard, or inconsistent with institutional policy. By passively directing choices in this manner, it is more likely that patients will receive safe, effective, and cost-efficient therapy.

TABLE 9-5.
Examples of Basic Structured Data Elements

- Generic drug name
- Dose amount
- Unit of measure (e.g., mg, units, mg/kg, mEq/L)
- Route of administration
- Frequency or rate of administration
- PRN
- PRN reason
- Dispensing dosage form (e.g., tablet, capsule, suppository)
- Dispensing strength and amount
- Administration times

mEq/L: milliequivalents per liter; mg: milligrams; mg/kg: milligrams/kilograms; PRN: as needed

The use of structured order entry also ensures key clinical information contained in the PIS or EMR system can be coded.²⁸ Coding of information allows the system to be used for *active CDS*. Active CDS conveys knowledge to the system's user. Examples of active CDS include system highlighting of abnormal laboratory values with color coding or arrows to denote the status of the reported value relative to the normal range and the use of pop-up alerts performed at the time of order entry such as system-initiated clinical checking for allergy problems, drug interactions, abnormal doses, therapeutic duplication, IV drug admixture incompatibilities, therapeutic indication problems, and other rules. For some of these basic types of decision support alerts, the clinical knowledge content is most often provided by third-party knowledge base products that are designed to be easily incorporated into the CDS offerings of EMR systems or PIS. The EMR or PIS vendor will then embed proprietary code or rules into their software to use this content for these basic alerts.

Clinical Decision Support Rules

A **CDS rule** is a coded logic program incorporated into the EMR system, the PIS, or a stand-alone CDS system to identify specific clinical care or business-related situations for the purposes of alerting specified users of the need to address a particular situation. CDS rules can be embedded rules created by the vendor or rules conceived by hospital employees. The clinicians most frequently see the end product of rules in the context of patient care alerts. Rules can take information from disparate systems, perform calculations, and/or incorporate logic to determine whether or not an alert should occur and then invoke that alert via a user-defined alert process.

Alerts and Knowledge Source Links

The already substantial medical literature increasingly grows over time. It is very difficult, if not impossible, for clinicians to stay adequately informed about best practices on their own. Hospitals can utilize the collective knowledge of all of their physicians and departments to create best practice guidelines for the majority of high-volume diseases. **CDS alerts** and links to both internal and external knowledge sources can be used to provide clinicians with warnings, supportive prompts, or access to clinical content to ensure they have the best tools at their disposal to care for their patients.

Active conveyance of clinical knowledge content is generally provided through alert and warning screens provided to the user but may include notification of alerts via printed documents, electronic mail, and pagers. CDS alerts can be embedded as a part of most any clinical information system, but it is frequently seen in PIS, inpatient or ambulatory care CPOE systems within EMRs, or as standalone expert systems that collate data from existing clinical databases for supporting the diagnosis, surveillance, and/or treatment of disease. The proper use of CDS requires not only the wisdom and experience of healthcare professionals but also clinicians understanding the capabilities, limitations, and deficiencies of CDS within their environment.

There are two main types of alerts that can be presented to users^{29,30}:

1. *Synchronous CDS alerts* represent pop-up warning screens that interrupt user workflow. They are generally triggered (invoked) based on specific actions taken by the system's user. An example of a synchronous alert might be the appearance of a drug dosing warning alert notification screen triggered when a user attempts to enter an excessive dose of a medication. The user action of submitting the order invokes a check of the dose against defined criteria within the system and interrupts the user with a request to act on the alert notification before proceeding.
2. *Asynchronous CDS alerts* generally occur as a result of an embedded rule and typically do not interrupt workflow unless the user chooses to do so. Asynchro-

nous alerts can occur based on programmed logic using data already contained within the EMR system database resulting from user input *or* from data sent to the database from ancillary systems. For the former, one example might result in a notification flag being placed on a nursing patient list when the clerk documents that the patient has left the unit for a physical therapy appointment. For the latter, the CDS system might examine laboratory results introduced to the EMR system via an interface with the laboratory information system to see if they are included as part of a rule. If so, and if the rule criteria stipulate that an alert notification

should occur, then the system will present the alert notification to a given user or category of users. An example of an asynchronous alert could be having a flag placed on a user's electronic work list, patient list, or system inbox when an abnormal laboratory value is manually entered or electronically transmitted to the EMR system for a blood chemistry test. Alternative asynchronous methods, such as email notices and paging, can be used to notify staff of a needed action based on system-defined criteria.

KEY POINT . . .

The proper use of CDS requires not only the wisdom and experience of healthcare professionals but also clinicians understanding the capabilities, limitations, and deficiencies of CDS within their environment.

. . . SO WHAT?

CDS relies on three things—a good CDS system, clinical expertise of the professional, and an understanding of how the CDS system can be used to improve the medication-use process. The CDS system can never take the place of the professional, and the professional should never rely on the CDS to make the final decision on a course of action.

INFORMATION SECURITY/CONFIDENTIALITY

Vulnerabilities and threats to information security may consist of internal failures of hardware or software, human errors, deliberate attacks on information security (cyber attacks or hacking), and natural catastrophes. Pharmacists responsible for informatics must ensure that the security design for all PISs support the prevention, detection, and correction of these vulnerabilities and threats.

Standards for **information security** are defined by the Federal Information Security Management Act of 2002 as the classic triad of **confidentiality**, integrity, and availability.³¹ Confidentiality ensures personal privacy protection and protection of proprietary information; integrity guards against improper modification or destruction of data; and availability ensures the timely and reliable access to and use of information. This model was expanded by Cherdantseva and Hilton in 2013 to include five additional dimensions that were inferred, but not explicitly stated: privacy, **nonrepudiation**, authenticity/trustworthiness, accountability, and auditability.³² Privacy is an extension of confidentiality and requires that the system follows all applicable laws and, where possible, allows individuals to control the use of their personal information. Nonrepudiation and authenticity/trustworthiness are an extension of integrity and ensure that someone cannot deny having conducted a transaction (nonrepudiation) and that system has the ability to verify the identity of and establish trust for a third party and the information the third party provides (authenticity/trustworthiness). Often, the term **authentication** will be used to describe

the process of accessing secure software. *Accountability* is the ability of a system to hold users responsible for any actions they take, such as misuse of information. *Auditability* is an assurance that all actions performed by humans or machines in the system can be monitored and cannot be bypassed. *Availability* ensures that all sections of the system remain functional and available to end users.

Approaches to securing information and systems vary depending on the degree of sensitivity of the information. One of the first steps is to ensure that the physical location where servers are stored has been secured. Access to a network should be limited to those who need it, and control must be exercised by a combination of security methods (e.g., passwords, smartcards, biometric identification). These methods provide for authentication of individuals accessing information to help ensure that only authorized individuals access the data. Furthermore, they provide for a history of access that can be examined if there are ever questions about who accessed certain data or was involved in specific transactions. Passwords are ubiquitous in current systems. However, a disadvantage is that they do not provide positive identification of individuals (passwords may be shared by multiple individuals). Organizations are moving toward multifactor authorization as a means to verify your identity when you log in. This involves the use of at least two of three components: something you know (e.g., password), something you have (e.g., physical random number generating token code), or something you are (biometrics). **Biometrics**, such as fingerprint recognition or retinal scanning, are becoming more prevalent due to their ability to provide a more positive authentication of an individual.

A practical security consideration with pharmacy systems is the ability to back up data so that they can be restored in the event of internal hardware or software failures. Backing up data sets may be accomplished by replicating the data in an alternate medium and location. Media that may be used include hard drives, tapes, CDs or DVDs, or other servers. The availability of adequate back-up systems is essential to protect against natural disasters as well as hardware or software failures. Critical applications are often created with redundancies built to protect against such failure, including the use of off-site data centers in the event of major local failure.

Another key security issue that has arisen with the advent of electronic transmission of prescriptions between physicians and pharmacies (and, in particular, Internet pharmacies) has been the authenticity of the involved parties and the electronic signature. In response to public concern for the safety of pharmacy practices on the Internet, the National Association of Boards of Pharmacy (NABP) developed the **Verified Internet Pharmacy Practice Sites (VIPPS)** program in the spring of 1999.³³ A coalition of state and federal regula-

KEY POINT . . .

Information security includes concerns about confidentiality, integrity, availability, privacy, nonrepudiation, authenticity/trustworthiness, accountability, and auditability.

. . . SO WHAT?

Information security considers multiple issues. It must ensure that only intended recipients can read the data. To maintain confidentiality, individuals accessing the system need to provide some authentication that they really are allowed to access the information. After taking an action within the system, individuals have to be held accountable for their actions. These issues are the foundation of CPOE, EMRs, controlled substance medication ordering and usage, and any other critical system in an institution.

tory associations, professional associations, and consumer advocacy groups provided their expertise in developing the criteria which VIPPS-certified pharmacies follow.

Pharmacies displaying the VIPPS seal have demonstrated to NABP compliance with VIPPS criteria. To achieve accreditation, a pharmacy practice site must comply with the licensing and inspection requirements of the states in which it does business and must demonstrate to NABP compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, maintenance of a quality assurance and improvement program, and provision of meaningful consultation between patients and pharmacists.

Systems such as **VeriSign™** are available to encrypt prescription or other protected health information during the electronic transmission of these data. This prevents the interception and unintended disclosure of confidential patient information during these transactions. Any pharmacy systems that involve transmission of patient data need to have a reliable and effective **encryption** process to assure confidentiality and authenticity.

While maintaining patient confidentiality and the security of patient information that has long been a tenet of practice among pharmacists, the requirements of healthcare providers were increased with the passage and implementation of the Health Insurance Portability and Accountability Act (HIPAA).³⁴ Two goals of this legislation were to improve efficiency in healthcare delivery by standardizing electronic data and interchange and to protect the confidentiality and security of health data through setting and enforcing standards. The impact of HIPAA on institutions has been an increased awareness of the security and confidentiality of protected health information. Health systems must conduct detailed assessments of their computer systems to ensure that appropriate privacy protections are in place and that the security of systems is adequate. In many cases, this has resulted in updating information systems to safeguard protected health information (PHI) and to enable the use of standard claims and other electronic health transactions. From a security perspective, HIPAA requires institutions to ensure the confidentiality, integrity, and availability of all electronic PHI that the institution creates, receives, maintains, or transmits. It requires the hospital to protect against any reasonably anticipated threats or hazards to the security or integrity of this information as well as ensure that rules and safeguards are in place to prevent inappropriate disclosure of this information. Within HIPAA, disclosure of PHI is limited to the minimum needed for healthcare treatment, business operations, and quality improvement.

KEY POINT . . .

HIPAA has attempted to standardize electronic data and interchange and protect the confidentiality and security of health data.

. . . SO WHAT?

HIPAA is a driving force behind many of the efforts to improve information systems within institutions. Many informatics systems in institutions and the policies and procedures in institutions regarding informatics have been formed by HIPAA.

One technique that may be useful when handling protected health information is to use encryption of patient identifiers. Encryption involves replacing identifiers that are traceable to an individual with another set of letters or numbers, which cannot be linked back to individual patients. This technique of **de-identification** is very useful when doing analyses of aggregate data sets, examining overall prescribing trends, and evaluating drug utilization when there is no need to identify patients specifically.

CLINICAL INFORMATICS PHARMACIST

From a practical perspective, pharmacist positions in clinical informatics have evolved in response to contemporary pharmacy practice needs rather than from an expressly designed role containing a clear academic and training path and aptitude. In general, pharmacists who accept these practice roles have either a strong interest in informatics or have developed a specific informatics aptitude on the job. The growth of the number of professionals with responsibilities related to informatics was a driving force behind the creation of a section within ASHP devoted to enhancing networking opportunities and “improving health outcomes through the use and integration of data, information, knowledge, technology, and automation in the medication-use process” (the Section on Pharmacy Informatics and Technology).

The need for pharmacists to have an understanding of pharmacy informatics has also led to the incorporation of informatics learning outcomes for both colleges of pharmacy and residency curriculums. The latter statement highlights an important point—that informatics pharmacists have a role in academia. With the explosion of technology, pharmacists need to remain on the forefront of that growth not only in practice but also in education and research. Knowledgeable faculty are needed to teach pharmacy students about informatics, and little research has been conducted on these new technologies. Pharmacists should collaborate in and lead research that evaluates the effectiveness of clinical decision support, the usability of technologies, and the impact on medication safety, departmental efficiency, and patient outcomes.

Roles and Responsibilities

Pharmacists who specialize in informatics generally are responsible for configuration and support of one or more of the following activities:

- Inpatient pharmacy information systems/EMR subsystems
- Outpatient pharmacy information systems/EMR subsystems
- Inpatient order entry/EMRs
- Outpatient order entry/ePrescriber systems
- Clinical decision support
- Robotic unit dose dispensing machines
- Automated medication dispensing machines
- Point-of-care BCMA
- Automated IV admixture devices
- Workflow management and tracking systems
- Packaging machines
- Programming
- Queries and report writing
- Inventory control systems
- Pharmacy intranets
- Customized pharmacy applications
- Desktop and application support
- Staff training and education
- Student and resident education
- Mobile health applications
- Informatics-related outcome assessment
- Informatics-related research

Education and Training

Pharmacists who wish to pursue a position in pharmacy informatics can accomplish this goal in several ways. *One option* is to take specific courses or obtain a degree in computer science, medical informatics, computer information systems, and/or business information technology. Useful coursework would include areas such as network administration, basic programming, database management, and heuristics. *Another option* available to pharmacists would be to complete an advanced residency in pharmacy informatics. Many sites for informatics residencies exist, and more continue to be created. Advanced residencies offer a wide array of learning opportunities not generally available to most pharmacists or pharmacy practice residents. *A third way* is to volunteer to assume an informatics role at one's current place of employment. This can be done by indicating an interest in informatics, volunteering to take responsibility for one or more aspects of informatics, and/or obtaining as much on-the-job experience as possible (e.g., taking coursework through local community colleges, attending certified training or vendor training courses, attending informatics-related conferences, learning from colleagues).

FUTURE DIRECTIONS

The field of pharmacy informatics is rapidly growing and constantly evolving. New opportunities are continuously emerging. Specific areas where pharmacists can serve as leaders include:

- Technologies that promote medication adherence (pill box/refill reminders)³⁵
- Remote monitoring of the effects of medications use (fitness tracking, wearable devices, digiceuticals, and mobile health applications)³⁶
- Monitoring of the effectiveness of medication use on populations (surveillance systems and the associated analytics)
- Tracking and reporting of data related to pharmacy operations, clinical effectiveness of drugs and drug costs (business intelligence and data visualization)²¹⁻²⁵
- Designing CDS rules using best practices derived from data taken during the process of providing real-world, routine patient care (learning health systems)³⁷

Many pharmacists have found applying their clinical knowledge with information technology skills for the purposes of bettering patient care to be a very satisfying and rewarding career. Emerging technologies offer pharmacists exciting new opportunities to improve patient care and expand their careers.



SUMMARY

Pharmacy informatics is a broad and growing area that can be defined as the application of information sciences to pharmacy practice and the medication-use process. Pharmacists use data and translate it to information that can be used in conjunction with their knowledge to improve the quality of patient care. Pharmacy informaticists work with medication-related information systems and automated technologies to help pharmacists make excellent decisions about ensuring optimal medication safety and security, patient care, departmental efficiency, and drug therapy costs within health systems.

Technology tools, in the hands of properly trained pharmacists, have the potential to greatly improve the safety and efficiency of the medication-use system in healthcare organizations. Pharmacy informatics has developed to the point that it has become its own discipline within the domain of pharmacy, and informatics pharmacists are playing

supporting and even leading roles in the management and use of most existing technologies designed to improve the medication-use system. Informatics pharmacists can ensure the confidentiality and security of patient information stored in these systems by promoting the use of biometrics and other forms of positive authentication. Although the role of informatics pharmacists has become well established, opportunities exist for pharmacists to serve in supporting and leadership roles in academia and with many newly emerging, medication-related technologies.

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CHAPTER REVIEW QUESTIONS

1. **Synchronous CDS alerts represent warning screens that are invoked based on a system user's specific actions and require the prescriber's immediate action.**

- a. True
- b. False

Answer: b. True. Synchronous CDS alerts usually flag problems that must be taken care of immediately (e.g., a notice of a potentially severe drug interaction). Therefore, they generally demand immediate attention and require some action on the part of the user before further actions can occur. Asynchronous CDS alerts occur independently of the order entry process and do not typically interrupt the user.

2. **A clinical data repository (CDR) is used to store _____ clinical data, which are used to provide a unified view of data from a variety of sources.**

- a. Physician-specific
- b. Patient-specific
- c. Pharmacist-specific
- d. Institution-specific

Answer: b. Patient-specific. CDRs contain data on individual patients collected from interconnected databases (e.g., pharmacy and laboratory) throughout the institution. The data are consolidated in the CDR to provide decision makers with a unified view of a single patient's clinical information.

3. **Which of the following is an accreditation program that provides a means for the public to distinguish between legitimate and illegitimate online drug sellers?**

- a. CPOE
- b. RFID
- c. HIPAA
- d. VIPPS

Answer: d. VIPPS. The VIPPS was created by the NABP to accredit pharmacy websites to provide a seal of approval for the public to distinguish between legitimate and illegitimate online drug sellers. The VIPPS seal of approval ensures that VIPPS retailers are legitimate online pharmacies appropriately licensed in each state to which they ship pharmaceuticals.

4. **Expertise and skills acquired by a person through experience or education is a description of:**

- a. Data
- b. Information
- c. Knowledge
- d. None of the above

Answer: c. Knowledge. Data are pieces of information that become knowledge when they are aggregated in a meaningful way. Information is data with relevance or purpose; in other words, information has contextual meaning.

5. Which of the following are benefits of electronic information sources compared to traditional paper information sources?

- a. Improved accessibility of information
- b. Reduced space requirements
- c. Ability to maintain up-to-date information
- d. All of the above

Answer: d. All of the above. Professionals anywhere inside and even outside of the health-care system can access electronic information. The electrons used to store the information take up little space, and changes can be made immediately and throughout the entire information system.

6. Radiofrequency identification is the use of a radiolabeled drug isotope to detect the extent of urine elimination of a drug from the body for more accurate pharmacokinetic monitoring.

- a. True
- b. False

Answer: b. False. Radiofrequency identification (RFID) is the use of an object (typically referred to as an RFID tag) applied to or incorporated into a product or person identifier (wrist band) for the purpose of identification and tracking using radio waves.

7. Societal drivers, which are spurring the development of new technologies, include which of the following:

- a. Governmental policies incorporating quality as a factor in health-system reimbursement models.
- b. The reduced need for specialized security systems in hospital intranets.
- c. The preferential use of on-site health care clinics instead of remote monitoring devices.
- d. All of the above

Answer: a. Governmental policies incorporating quality as a factor in health-system reimbursement models. The government is increasingly using patient outcomes, such as readmission rates, as incentives to ensure optimal value is achieved for the care provided. New technologies are emerging to optimize patient care through enhanced monitoring, care reminders, and provider communication. The level of connectivity has increased the need for system security. Remote monitoring is important for monitoring and collecting data on patients' health statuses without the need for more intensive clinic visits.

8. Privacy is an extension of confidentiality and requires that the system follows all applicable laws and, where possible, allows individuals to control the use of their personal information.

- a. True
- b. False

Answer: a. True.

9. Which of the following methods is best at positively authenticating individuals for purposes of enhancing information system security?

- a. Passwords
- b. Bar code scanning
- c. Biometrics
- d. None of the above

Answer: c. Biometrics. Authentication provides protection against unauthorized access or forgeries. It is possible for others to borrow or steal other people's passwords and bar-code badges. Fingerprints and scans of the retina are harder for unauthorized individuals to acquire and use.

10. Pharmacists who wish to pursue a position in pharmacy informatics can accomplish this by:

- a. Obtaining a degree in computer science, information systems, and/or business information technology.
- b. Completing a PGY2 residency in pharmacy informatics.
- c. Assuming on-the-job responsibilities and networking with other individuals in pharmacy informatics.
- d. Any of the above

Answer: d. Any of the above. There is no single path to acquiring an informatics position. One path is to obtain a specialized degree that offers training relevant to informatics duties. Many different types of varying quality are offered, so it is important to choose carefully before enrolling. A less formal path is to identify a healthcare system offering a PGY2 residency specializing in pharmacy informatics. These are still rare but becoming increasingly common. A third option is to just do it, by volunteering to help out with informatics projects. On-the-job training and networking with experts in an institution is the way many pharmacists gained informatics expertise. When needed, they typically sign up for training offered by the health system or seek out training opportunities in the community. Ultimately, any path can be justified because the real test of an informatics pharmacist is his or her ability to manage and solve technology problems.

CHAPTER DISCUSSION QUESTIONS

- 1. Distinguish the different types of clinical decision support that can be employed and the situations and reasons where one method might be used instead of an alternate method.
- 2. Discuss the many sources for drug information available to patients and explain how pharmacists can help direct patients and their family members to valid sources of drug information.
- 3. Explain the rationale for coding information in EMR/PIS/CPOE systems where clinical decision support will be used.
- 4. Describe the various roles for informatics pharmacists in health systems and the scope of training that is required to perform these activities.
- 5. Describe three vulnerabilities and threats to information security and discuss the steps that institutions can take to minimize or mitigate those threats.

Electronic Data Management: Electronic Health Record Systems and Computerized Provider Order Entry Systems

Asli Ozdas Weitkamp, Scott D. Nelson, Shane Stenner, and S. Trent Rosenbloom



LEARNING OBJECTIVES

After completing this chapter, readers should be able to:

1. Describe key elements of any system of electronic health data, information, and knowledge management.
2. Define key terminology associated with electronic health data management systems.
3. Identify major issues associated with the use of electronic health data management.
4. Explain the role of pharmacists in electronic health data management.



KEY TERMS AND DEFINITIONS

- **Clinical data repository:** A type of database that contains patient information including lists of medications; allergies; laboratory and radiology testing results; vital signs documentation; clinical documents; demographic information such as age, gender, and address; and orders.
- **Clinical decision support (CDS):** Tools that deliver guideline- or knowledge-based information to healthcare providers and patients as they interact with a clinical system.
- **Computer-based documentation systems:** Systems that prompt clinicians to provide complete information when documenting their clinical decisions and patient interactions. These systems may require data fields to be completed or reviewed (e.g., allergies) before allowing clinicians to proceed with other tasks.
- **Computerized provider order entry (CPOE):** The process in which health-care providers electronically create clinical orders (e.g., prescriptions, laboratory, radiology requests) using a specialized interface to a computerized orders database.
- **Data standards:** Predefined formats, structure, and content for information about patient or healthcare processes, such as that stored in a clinical data repository.
- **Electronic health record (EHR) system:** A clinical system designed to store, manage, and display healthcare-related records, including all clinical and administrative information entered by all practitioners involved in healthcare delivery.
- **Electronic medical record (EMR):** A clinical system containing computerized clinical documentation of a patient's medical care over time within a single institution (e.g., hospital, physician's office).
- **Electronic prescribing (e-prescribing):** Computerized clinical systems typically used in ambulatory care settings to manage and create medication prescriptions, sent electronically between prescribers, pharmacies, pharmacy benefit managers, and insurance plans.
- **Functionality:** Defined as the sum of all things (i.e., functions) that a software program or system can do for users.

- **Health Insurance Portability and Accountability Act (HIPAA):** Legislation enacted in 1996 to improve portability and continuity of health insurance coverage in the group and individual markets; to combat waste, fraud, and abuse in health insurance and healthcare delivery; to promote the use of medical savings accounts; to improve access to long-term care services and coverage; to simplify the administration of health insurance; to restrict unauthorized access to clinical data; and for other purposes.
- **Health Level-7 (HL-7):** One of several data standards-setting organizations whose mission is to support interoperability for EHR systems.
- **Interoperability:** The ability of clinical information systems to exchange and use data from other such systems; it often relates to the usage of shared data standards.
- **Meaningful Use:** A program introduced through the U.S. Health Information Technology for Economic and Clinical Health (HITECH) Act, to financially incentivize healthcare providers to use EHRs.
- **Personal health record (PHR):** A clinical system accessible to and controlled by patients and their caregivers that contains information about their own medical care and insurance coverage. These may be web-based or app-based and can be standalone or tethered to an institution's EHR system. The PHR commonly contains person-friendly tools (e.g., weight control monitoring and guidance) to help individuals manage their personal health.
- **User interface:** The point at which a user interacts (i.e., interfaces) with a computer program or device. The user interface is often at a stationary computer screen or on a mobile device.



INTRODUCTION

Electronic clinical data management in health systems revolves around two forms of technology: **electronic health record (EHR) systems** and **computerized provider order entry (CPOE)** systems with integrated **clinical decision support (CDS)**. Both have the potential for transforming medical care in institutions and pharmacy practice by improving access to comprehensive, accurate, and timely information about patients, their care, and relevant clinical knowledge. We note that CPOE systems with integrated CDS refer to advanced systems with decision support algorithms fully embedded into order entry workflows. In such systems, users interact with a decision support module that guides them through clinical problem-solving, with clinical orders being an output of the process. This is differentiated from a traditional order entry system in which healthcare providers type in only patient orders, without special context or guidance from integrated CDS.

EHR systems are computer-based applications designed to acquire, store, manage, and display healthcare-related records, including all clinical and administrative information entered by those involved in healthcare delivery.¹ Although the potential for EHR systems to improve healthcare quality and value is widely accepted, adoption remained limited until the Affordable Care Act's **Meaningful Use** program incentivized adoption starting after 2010.^{2,3} The reasons for limited EHR adoption postulated in the scientific and lay literature include the high cost of developing and maintaining such systems, the unclear return on EHR investments, physician resistance, and an inadequate number of individuals trained in information technology. The Meaningful Use program drove EHR system adoption such that now they are nearly universally adopted in major settings of healthcare delivery within the United States.

CPOE with CDS is the process by which healthcare providers interact with specialized, knowledge-based tools and algorithms to address clinical problems, resulting in the system placing clinical orders (e.g., prescriptions, laboratory testing requests). In a 2014 survey, 80.9% of hospitals reported that they used CPOE systems with CDS,⁴ and this number is expected to grow due to ongoing national mandate, legislation, industry incentives, and stakeholder pressure.^{3,5-7} Although CPOE systems support multiple order types (i.e., radiology, dietary, laboratory), the focus of this chapter will be on the medication component.

To cover these main issues, this chapter is divided into two sections. The *first section* focuses on EHR systems including the evolving definition of EHR systems, the information contained in an EHR system, and the role of an EHR system in healthcare. The *second section* describes CPOE and its role in improving healthcare prescribing.

ELECTRONIC HEALTH RECORD SYSTEMS

The history of EHR systems began in the early 1960s, with early pioneers developing programs to assist in documenting patient history, physical examinations, and radiology reports.⁸⁻¹⁰ Some of the earliest EHR systems include The Medical Record (TMR), developed in 1970 at Duke University; the Regenstrief Medical Record System (RMRS), first developed in 1972; and Intermountain Healthcare's Health Evaluation through Logical Processing (HELP) system in Utah.^{1,8,11-13} Since then, many EHR systems have been developed in academic settings across the country. Examples include the COSTAR project at Massachusetts General Hospital and systems at Stanford, Johns Hopkins, Columbia, and Vanderbilt.¹⁴ In addition, the U.S. government has developed an EHR system for the Department of Veterans Affairs, and many commercial vendors have been creating or licensing additional systems in the private sector.¹⁵ Since 2010, the federal Meaningful Use program has used a series of financial incentives and penalties to drive EHR system and standards adoption. This program laid out a series of functional requirements for EHR system developers as well as usage requirements for system users, released in stages. Currently, the program has outlined three stages of functional requirements and usage criteria.

As EHR systems have evolved, the terminology associated with electronic records has too, resulting in confusion over the terms electronic health record, electronic medical record, and personal health record. An **electronic medical record (EMR)** defines the computerized clinical documentation of a patient's medical care over time within a single institution (e.g., hospital, physician's office). The EMR is essentially the electronic equivalent of a paper-based medical record. In contrast, an EHR encompasses documentation of all episodes of patients' medical care received over time within a geographic area. Information in an EHR may be compiled from data in EMRs in multiple institutions. A **personal health record (PHR)** system is typically a web-based or app-based platform accessible to and controlled by patients and their caregivers, which contains information about their own medical care and insurance coverage. A PHR system commonly contains patient-friendly tools (e.g., weight control monitoring and guidance) to help patients manage their personal health. To maintain consistency and avoid confusion, this chapter will use only one term, *electronic health record*, to describe the electronic medical documents in institutions whether they originate from a single institution or an integrated health system.

In general, EHR systems have been designed to replicate the information found in traditional paper-based medical records but often take on greater **functionality** (i.e., do more things for users).¹⁶ **Figure 10-1** illustrates some of the key data entered into the EHR. The value of EHR lies in how it integrates various information sources into an accessible, useful form for individuals.

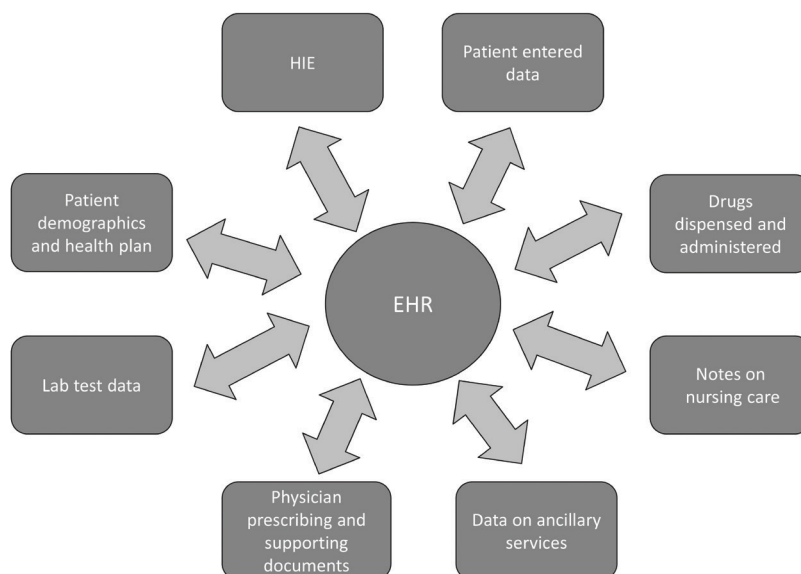


FIGURE 10-1. Key data flows to electronic health record systems.

EHR: electronic health record

A major goal of EHR systems is to provide secure, real-time, point-of-care and patient-centered information for all healthcare providers.¹⁷ This means that they make patient care information available wherever it is needed, 24 hours a day, 7 days a week. EHR systems can remind and advise healthcare providers, provide easily retrievable information about care given days or years before, and coordinate the efforts of all parts of the healthcare system. High-quality EHR systems help clinicians manage multiple aspects of patient care (e.g., clinical documentation, medication and allergy management, laboratory results tracking) and promote better decision making by providing accurate and timely clinical information. They can coordinate patient care across different sites of healthcare delivery, support administrative functions related to scheduling patients' admissions or appointments, and organize information according to what is needed and when it is needed. Information extracted from EHR systems can be used for quality assurance monitoring and medical research. In the United States, EHR systems must now also be designed to meet **Health Insurance Portability and Accountability Act (HIPAA)** patient privacy requirements and Meaningful Use Certification criteria.

EHR systems can include a series of linked electronic information management subsystems. These subsystems consist of a range of interconnected software applications (e.g., CPOE systems, laboratory data) that provide functionality to the overall EHR system. Comprehensive EHR systems generally contain several core components: a patient data repository, user interfaces, CDS modules, computer-based documentation systems, and CPOE (**Figure 10-2**). A **clinical data repository** is generally a type of database that contains patient information including lists of medications; allergies; laboratory and radiology testing results; clinical documents; demographic information such as age, gender, and address; and orders. Data can be stored as narrative free text, coded, graphical, picture, or multimedia forms. The information available in a patient data repository can be displayed in or inform the functioning of other tools within an EHR system. **User interfaces** are the point of communication between users and the EHR. User interfaces are stationary computer screens or mobile devices that allow healthcare providers to interact (or inter-

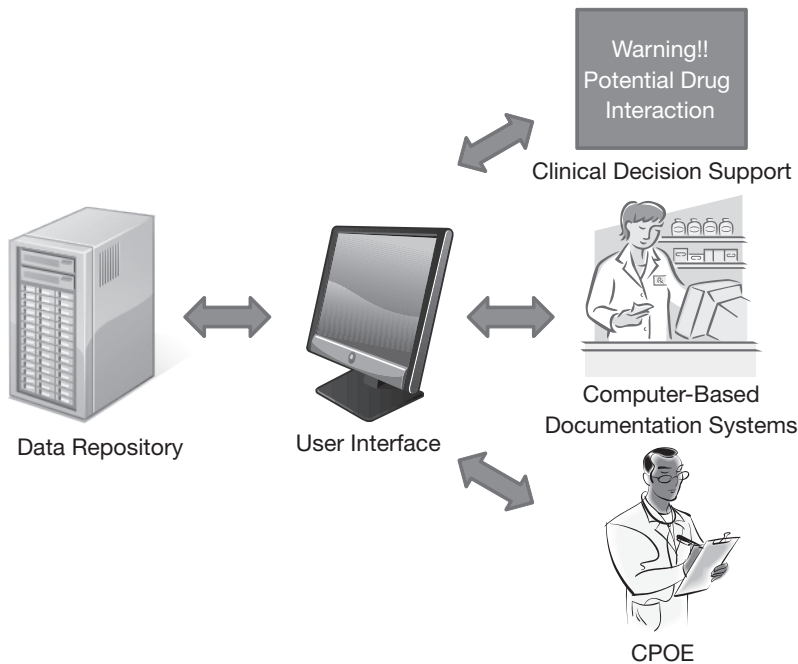


FIGURE 10-2. Common components of EHR systems.

CPOE: computerized provider order entry

face) with the data in a patient data repository. User interfaces are essential for the basic work of medicine including the entry of new orders or prescriptions, viewing of laboratory reports, scheduling clinical visits or admissions, and managing lists of diagnoses. CDS tools guide and advise clinicians as they interface with the EHR. CDS tools provide feedback about the best available evidence from national professional society clinical guidelines and other expert sources. Decision support can be as simple as providing lists of the available dosage forms during order entry or as complicated as expert guidance for complex therapies such as total parenteral nutrition or chemotherapy, incorporating data on laboratory results, current diagnoses, and concurrent medications. **Computer-based documentation systems** assist healthcare providers in documenting their clinical decision making and patient interactions. They prompt clinicians to fill in data fields that better document their clinical decisions and patient interactions. CPOE will be discussed later in this chapter.

One of the problems often seen with EHR systems is their current lack of **interoperability**, which is the capability of information system components to exchange and use data from other systems. Interoperability has been problematic because many EHR systems are made of different tools

KEY POINT . . .

EHR systems are tools that provide secure, real-time, point-of-care, and patient-centered information for all healthcare providers.

. . . SO WHAT?

EHRs are replacing paper health records, largely due to the Meaningful Use program. This transition to EHRs provides additional functionality and has impacted the ways in which pharmacists, physicians, nurses, and others provide care for patients.

Pharmacists are active users of the EHR and play a critical role in CPOE, e-prescribing, and CDS.

developed in isolation from the others, often by different software companies, and with each serving one or more of the functionalities. For example, a system might have one software program that links the data repository to a clinical capture tool but a different system is used for CDS. When different systems interact as part of an interfaced EHR, there is greater potential for system malfunction than when they are developed as part of an integrated system. In this scenario, additional software might be needed to integrate the EHR components and manage the data flow among them. Efforts driven by the federal Meaningful Use program have encouraged interoperability. Examples include an emphasis on certain data standards for representing clinical information in EHR systems, the usage of the Consolidated-Clinical Document Architecture (C-CDA) standard for clinical data sharing, and certification requirements around common EHR system functionality.

BENEFITS OF EHR SYSTEMS

EHR systems provide a number of direct benefits to healthcare providers including physicians, nurses, pharmacists, and therapists. One key benefit results from the fact that patient information is not tied to a single location as it is with a paper chart. Access to the data is not limited either—clinicians and managers can view health record data simultaneously, throughout the healthcare system (e.g., in the Emergency Department, on a nursing unit, at the pharmacy). Another benefit is that data can be automatically captured and stored as part of the overall workflow—information entered at keyboards or other data capture devices flows directly into an EHR system. Errors can be reduced with EHR systems because medical information entered into the system is immediately legible, thereby reducing the potential of miscommunication between system users.

One of the major benefits of EHR systems is the wealth of automated solutions and data they can provide to support efforts around quality assurance and continuous improvement.¹⁴ Clinical documentation tools, for example, can improve legibility and reduce medication and documentation errors. EHR systems can aggregate performance information by disease, by healthcare providers, and patient care area. Such performance information can identify where clinical practice benchmarks are not being met. In some cases, EHR systems can be connected directly to medical devices such as infusion pumps or heart monitors and trigger alerts when patients have a significant change in status.¹⁸ EHR systems may also include decision support to help improve compliance with regulatory society standards, such as those published by the Joint Commission by increasing the ability to manage and store data.¹⁹

In addition to improving medical practice and management, EHR systems can support clinical research efforts. Data from large patient populations can be extracted to answer questions such as “Which treatment works best for this patient suffering from the following medical conditions?” Without an EHR system, gathering information manually is tedious, inefficient, slow, and prone to error. With EHR systems (under ideal conditions),

KEY POINT . . .

EHR systems contain a wealth of clinical data that can be used for quality assurance and performance improvement efforts.

. . . SO WHAT?

EHR systems can collect information from all patient records and allow professionals to combine them in useful ways. For instance, to facilitate medication reconciliation, an EHR contains information about a specific patient’s medication list, problem list, allergies, and laboratory results. These data can then be used to improve patient care for that specific patient or be aggregated across many patients to improve processes or quality assurance.

researchers can download information electronically from diverse locations quickly and economically. EHR systems are typically designed to improve the quality of data received by prompting clinicians to provide complete medical data (through clinical data capture tools), and that data can be made available for research shortly afterward. Once in the EHR, systems can automatically identify patients meeting inclusion criteria for research trials, thereby improving targeted recruitment.¹⁸

INFORMATION CONTENT AND DATA ISSUES WITH AN EHR SYSTEM

In 2009, the Institute of Medicine (IOM) developed a list of potential functionalities that could be incorporated in an EHR system.²⁰ With the Meaningful Use initiative, many of these functionalities were codified using incentives for vendors and users. These functionalities can be divided into the categories of clinical documentation, test and imaging, CPOE, and decision support:³

- Clinical documentation
 - Medication administration records
 - Medication lists
 - Nursing assessments
 - Physician notes
 - Pharmacy notes
 - Problem lists
- Test and imaging
 - Diagnostic-test images (e.g., electrocardiographic tracing)
 - Diagnostic-test results (e.g., echocardiographic report)
 - Laboratory reports
 - Radiographic images and reports
- CPOE
 - Laboratory tests
 - Medications
- Decision support
 - Clinical guidelines (e.g., beta-blockers after myocardial infarction)
 - Clinical reminders (e.g., pneumococcal vaccine)
 - Drug-allergy alerts
 - Drug-drug interaction alerts
 - Drug-laboratory interaction alerts (e.g., digoxin, low level serum potassium)
 - Drug-dose support (e.g., renal dose guidance)
 - Order sets (i.e., standardized lists of orders for a specific diagnosis)

Although there is general agreement on what information/data can be contained within an EHR system under ideal circumstances, two common problems occur in real life practice settings: difficulties in data input and system interoperability/information sharing. These issues limit the ability to collect and access good quality data.

The difficulties with data entry were articulated by McDonald in 1972 and remain to this day.^{1,2,8,9,17} Most EHR systems provide numerous ways to input patient data.²⁰ The earliest EHR systems permitted input using manual punch cards, which many system users believed were preferable to typed entry.^{8,17} Other developers experimented with patient-entered data using simple electronic questionnaires.²¹ Ultimately, the keyboard (or handheld key pad) has evolved as the primary means of data input. Other common methods of data entry

include direct interfaces with other computers that generate data (e.g., digital laboratory test analyzers, some blood glucose monitors), point-and-click entry into a computer form using a computer mouse or a touch-screen monitor, dictation and transcription, drawing using a specialized digital tablet, and scanning of handwritten documents.

Each method for data input has relative strengths and weaknesses. Typing, for example, may be efficient and acceptable for skilled users and relatively simple for data entry needs, but it is time consuming for others and limits the type of data that can be entered to what fits on a standard keyboard. Dictation with transcription is useful for those who cannot type efficiently, but it is expensive, error-prone, and requires a time delay before the dictated note is available in the EHR system. Point-and-click entry into structured forms can be very fast for simple data entry tasks, but it can become difficult and constrain input if users have difficulty finding data fields on the form. Handwriting and scanning offer providers tremendous flexibility and ease but may lead to reduced legibility and data availability.

A more daunting problem than data input is that entered information cannot always be shared with other systems. This problem arises when different systems (or tools within a single system) encode the same information using different words, codes, or narrative structure. The limited system-interconnectivity (i.e., interoperability) of components of EHR systems has played a major role in limiting their adoption and use. Although some issues related to interoperability have been addressed with the Meaningful Use initiative, interoperability between systems and system components remains a challenge. The problem of noninteroperability has arisen because vendors of EHR systems have customized their products for users. This customization has resulted in differing data categories and formats.

For example, it might be reasonable to assume that typing a patient's weight into the system is a simple act that results in the weight being subsequently available to all connected EHR component systems. In reality, capturing and sharing a data element like weight can be nuanced. One component of the system may store the data as "Weight," while another component stores it as "Wt." Still another component might store data about the patient's weight in free text, such as a physician's clinical note containing the unstructured narrative, "the patient weighs..." Additionally, it might be unclear if the stored weight is the patient's actual body weight, ideal body weight, dry or wet weight, etc. Sharing the patient's weight between these different systems is very difficult, if not impossible, without explicitly programming this one data element in a form recognized by all system components. Indeed, the problem is multiplied for every potential piece of patient data including medications, allergies, clinical findings, diagnoses, laboratory results, and orders.

KEY POINT . . .

The limited system interoperability and usability of components of EHR systems has played a major role in limiting their adoption and use.

. . . SO WHAT?

The healthcare system is not really a system; it is a collection of independent entities that are uncoordinated, even counterproductive in their actions. One of the main reasons is the inability of systems to communicate. Imagine if your cell phone lacked interoperability with other cell phones. You might be able to use some of the applications (e.g., games, calendar), but most of its value to you would be lost. Similarly, lack of interoperability between systems reduces the value of EHRs in coordinating and improving healthcare.

One solution to the problem of sharing information among systems is **data standardization**. Standardization defines a regular format for the data, the terms used to represent it, the configuration it should take, and the content the data represents. For example, one standard would state that physical measurements, such as weight, must include the measurement name (e.g., weight), the value (e.g., 70), and the units (e.g., kilograms). A corollary standard would state that weight must always be represented in EHR systems by the term “weight,” and a formatting standard would state that the three must follow a certain configuration (e.g., measurement = weight, value = 70, unit = kilogram).

A major standards organization, **Health Level-7 (HL-7)**, has been widely adopted as an industry data interchange standard. HL-7 primarily defines standards for data formatting and configuration. Data from two HL-7 compliant systems can communicate with relative ease and minimal additional programming. However, HL-7 generally stops short of defining standard terms for semantic data exchange (i.e., interoperability). The United States National Committee on Health and Vital Statistics and the Meaningful Use initiative have identified several core clinical vocabularies as terminology standards such as RxNorm for medications and LOINC for laboratory tests^{22,23}; unfortunately, these terminologies may be inconsistently available or adopted by system developers.²⁴

Enterprise information architecture can be a solution for problems with data exchange among EHR systems if they are widely adopted. Enterprise information architecture designs interoperability into the structure of information system design using compatible, logical suites of application programs. In the U.S. healthcare system, enterprise information architecture is the exception rather than the rule.⁵

COMPUTERIZED PROVIDER ORDER ENTRY

CPOE has been promoted as a strategy to reduce medical error. In 2000, the IOM published its first report on medical error, *To Err Is Human*.⁷ This report garnered a great deal of attention and galvanized many healthcare organizations to make patient safety the top priority, and brought attention to potential computer-based solutions to address patient safety gaps. A second report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, highlighted the importance of EHR systems and the use of CPOE to eliminate many of the preventable adverse events in the provision of care.²⁵ Medication errors are the most prevalent type of medical error with approximately 90% of them occurring at the ordering or transcription stage. By ensuring standardized, legible, and complete orders, CPOE systems have the potential to significantly reduce adverse drug events. The Leapfrog Group, a consortium of Fortune 500 companies interested in healthcare quality, specifically selected CPOE as one of the three recommended goals because of its potential to reduce harm to patients from medication errors.⁵

CPOE and electronic medication prescribing are key aspects of computer-assisted order generation. CPOE describes the process of electronic entry of orders into a health system’s EHR using a specific order entry module. **Electronic**

KEY POINT . . .

The IOM report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, highlighted the importance of EHRs and CPOE in preventing adverse events in healthcare.

. . . SO WHAT?

IOM reports are the basis of many changes in healthcare. Although it might be obvious to pharmacists, the fact that IOM has concluded widespread adoption of EHRs and CPOE are needed means that government entities and professional groups are given momentum to drive this change.

prescribing or **e-prescribing** refers only to CPOE pertinent to medications in ambulatory care settings. E-prescribing typically describes electronic transmission of prescription data among prescribers, pharmacies, pharmacy benefit managers, and insurance plans; CPOE transmits the orders to laboratory, dietary, radiology, nursing, and pharmacy services.

In their earliest forms, CPOE systems date back to the mid-1970s. Early systems allowed healthcare providers to enter orders directly into the system but provided little decision support to alert drug-drug interactions, allergy warnings, etc. System functionality, hardware limitations, and readiness of institutions limited early adoption. Over subsequent years, technical advancement and the necessity for tools to assist professionals in delivering ever-increasing complex care to patients have led to further adoption of CPOE.

In spite of these efforts, CPOE use did not move far beyond the first adopters until the announcement of the federal Meaningful Use program in 2010; prior to then, CPOE for medications was fully implemented in only 17% of all U.S. hospitals with 45% of hospitals having no CPOE or plans for CPOE in the near future.³ Several reasons for not adopting CPOE include (1) belief that physicians would not use computerized ordering, (2) products available from vendors had not reached a threshold of functionality and usability acceptable to users, and (3) technical and process complexities of implementing CPOE translate into a significant investment with no guarantee of success.^{26,27} Lack of standardization in practice across healthcare facilities is also cited as an additional barrier.²⁸ Since then, a 2014 survey of U.S. hospitals showed a substantial increase to 80.9% of hospitals using CPOE with CDS.⁴

KEY POINT . . .

In 2008, CPOE for medications had been fully implemented in only 17% of all U.S. hospitals; as of 2014, 80.9% of U.S. hospitals have fully implemented CPOE with CDS.

. . . SO WHAT?

U.S. hospitals had a long way to go to catch up with the 21st century. Many excuses are offered for lagging: physician resistance, expense, and difficulty of implementation. It was not until major federal incentives were put in place that CPOE adoption increased substantially.

IMPLEMENTING CPOE SYSTEMS

Advocates of CPOE systems promote their potential to reduce adverse events related to prescribing by alerting healthcare providers to possible errors (e.g., drug dosing, drug-drug interactions, patient allergies). Enthusiasm for CPOE has extended throughout the healthcare industry and into pharmacy circles. This interest is a result of many different stakeholders including healthcare facility leadership, standard and regulatory organizations, informatics professionals, software vendors, and the pharmacy profession. CPOE can be expected to achieve several goals²⁹:

- Improve patient safety
- Increase timeliness of care
- Facilitate use of current medical knowledge via CDS
- Improve the process and coordination of care
- Limit the missed opportunities for preventive care
- Provide research capability for epidemiological studies
- Control or reduce costs

Although implementation of a CPOE system can have an impact on every hospital department, the pharmacy often becomes a significant component of the process due to the complexity of processing medication orders, necessity of content management for medication-related decision support, volume of transactions associated with medication orders, and perceived value of CPOE on the medication order process.³⁰ Therefore, the pharmacy must be prepared and positioned to provide leadership and support for the medication component of a CPOE implementation. The pharmacist is well prepared and has historically demonstrated clinical and process skills in utilizing pharmacy computer systems.³¹ These skills must be combined with innovation and a desire to provide solutions for a successful CPOE implementation.

CPOE mirrors the basic steps associated with ordering any written prescription (**Figure 10-3**). The major difference, however, is that CPOE completes many routine ordering tasks electronically, reducing the possibility that information is overlooked or acted upon. The process starts with the ordering provider signing into the computer or system. The sign-in verifies the prescriber's identity and ordering privileges, thereby preventing any orders outside one's scope of practice. A patient is selected, and the patient's medical record is reviewed for any medication therapy in the case of an e-prescription. Once a need is established, the process of choosing the drug occurs. After accessing the CPOE interface, the user chooses a drug for the patient from a menu or by typing the drug name into a computer field. Dosage, route of administration, and other options are presented for the prescriber to select from along with any alerts or advisories relevant to the situation. When satisfied with the choice of an order, the prescriber authorizes the order, and it is sent to the pharmacy electronically or in print form.

In the pharmacy, the order is reviewed against the patient's medication profile or medical record and entered into the pharmacy system. Once in the pharmacy system, alerts and advisories are flagged for the pharmacist for action. After any potential problems with the prescriber are resolved, the medication is dispensed with directions and sent to the nursing unit for administration to the patient.

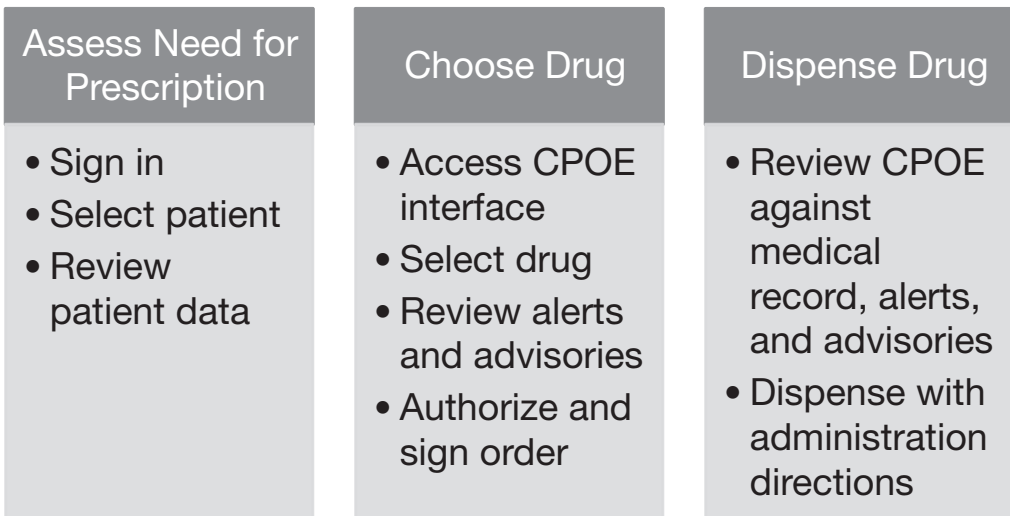


FIGURE 10-3. Basic steps in prescribing and dispensing a computerized provider order entry (CPOE) prescription.

CLINICAL DECISION SUPPORT

CPOE systems are often paired with some type of clinical decision support system (CDSS). The CDSS encompasses a variety of tools that augment the decision-making capabilities of the prescriber at appropriate decision points of an order entry process. The range of potential CDS includes simple reminders, interruptive alerts that require overrides, and complex algorithms to recommend or change therapy. CDS is a key element of effective CPOE systems.

Pharmacies have long employed CDS in pharmacy information systems. Functionality has traditionally included checking allergies, duplicate therapies, drug interactions, and abnormal dosage ranges. Although an important safety tool, most pharmacists would admit that CDSS tools are not always effectively embedded in CPOE workflows because many alerts are clinically insignificant while important alerts are often inadequately addressed. Furthermore, pharmacists have historically not been allowed access to patient demographic information, disease information, and laboratory values in many systems. In recent years, increased involvement of pharmacists in curating and monitoring the impact of medication-related CDS has significantly improved pharmacy integration and access. Pharmacist involvement is crucial to effectively monitor medication therapy.

All CPOE systems provide a basic level of passive or active decision support, although this functionality varies greatly with the product.³² *Passive decision support interventions* unobtrusively direct users toward the most appropriate practices and could be general or patient specific. Examples include order sets, limiting drop-down lists or check boxes, or sorting results or lists in a particular order. *Active alerts* can be noninterruptive or interruptive in how they are presented to the user. *Noninterruptive active alerts* present relevant patient-specific information to the prescriber without interrupting the prescriber's workflow. Examples include nonformulary alerts, drug shortages, and order sets. *Interruptive active alerts* utilize specific patient information combined with other clinical knowledge to recommend or change therapy by interrupting the prescriber's workflow to display the information. Examples include dosing recommendations, allergy warnings, and safer therapy, or less expensive treatment options.

CPOE vendors require drug-content modules (i.e., First Data Bank, Medi-Span, Multum, Micromedex) with their products that serve as the core of medication CDS. These systems typically provide alerts for drug-drug, drug-allergy, drug-pregnancy, and other drug-related interactions or ranges. One critical role for pharmacists is to access these systems to ensure that the majority of alerts are clinically significant and actionable while only a minimal number are clinically insignificant.

KEY POINT . . .

Pharmacists have an important role in ensuring that the majority of alerts in CDSSs are clinically significant and actionable.

. . . SO WHAT?

CDSSs are rough tools for alerting clinicians about medical problems. By design, they are conservative in their notification process, "When in doubt, notify." Pharmacists who have access to CDSSs can individualize the alerting process to the needs of their patient populations, medical staff, pharmacists, and system of medication control. For example, pharmacists at one institution might choose to activate alerts for clinically significant, drug-related problems, while pharmacists at another place might decide to alert for all potential drug-related problems. One institution might make clinically significant alerts active and interruptive, while other alerts are active yet noninterruptive. Access to CDS gives the pharmacists a choice.

Ideally, alerts should be generated only for clinically significant problems. However, clinical significance is often a judgment call that is best left up to the clinician. Therefore, commercial CPOE systems tend to conservatively put more alerts into a system than necessary, causing the problem of alert fatigue where the clinician is desensitized to warnings. Pharmacists have a particularly important role in identifying nuisance alerts from relevant alerts and developing strategies for reducing them. Pharmacists also have a role of updating systems to reflect the best available evidence on therapy. Most commercial systems allow pharmacists to deactivate nuisance alerts and add new alerts deemed clinically important for an institution’s patient population.

ASSESSING THE IMPACT

Maintaining and improving the quality of the medication-use process requires assessing the impact of CPOE. There are four possible outcomes for any CDS alert (Table 10-1).³³ Measures of success should also be clearly defined for the CPOE system with methods to track and evaluate these measures of success. Potential areas of evaluation are the following:

- Medication safety and adverse drug events
- Response time for medication processing
- Pharmacy resource needs
- Drug cost reductions and achieving financial targets
- Downtime and availability of system
- Response time of system
- Clinical alerts and action taken by provider

TABLE 10-1.
Four Possible Outcomes for Any CDS Alert

	Alert Generated	No Alert Generated
Correct alert	Alert for clinically significant problem. Example: allergy warning appears when penicillin is prescribed for a patient with a beta-lactam allergy. The clinician needs to see this alert because there is risk of harm to the patient.	No alert generated because of no problem. Example: No alert is generated when penicillin is ordered for a patient with no penicillin or beta-lactam allergies. There is no problem so the clinician does not need to see this alert.
Incorrect alert	Alert generated for a clinically insignificant problem. A duplicate drug warning for a patient receiving a therapeutically appropriate two antibiotic combination. The clinician does not need to see this alert because there is no risk of harm. This is a nuisance and a time waster. It may also desensitize the clinician to clinically appropriate alerts.	No alert generated for a clinically significant problem. NO allergy warning appears when a patient is prescribed penicillin but has beta-lactam allergies. The clinician needs to see this alert but does not due to a variety of causes including the patient allergy was not recorded, the allergy warning was not in the commercial package’s alert library, or the alert was blocked by the pharmacy department.

CDS: clinical decision support
Source: Adapted with permission from Rose E, Jones M. Clinical decision support. In: Dumitru D, ed. *The Pharmacy Informatics Primer*. Bethesda, MD: ASHP; 2009.

As with any complex system, it is imperative to monitor the performance with respect to clearly defined and agreed upon success criteria, provide feedback to all stakeholders, and make necessary adjustments to improve performance. This process encourages support and continuous improvement of the system. Not following such a continuous improvement process will introduce new opportunities for errors. Systems and processes must be in place to quickly identify performance issues so they can be managed aggressively.



SUMMARY

EHRs and CPOE with integrated CDS have a substantial impact on institutional pharmacy practice.^{34,35} With these systems in place, pharmacy technicians could oversee the processes of automated dispensing, IV pump management, and other distributive responsibilities. These increases in automation and efficiency will move pharmacists from distribution to more active clinical roles. Pharmacists who do not advance their pharmaceutical care and clinical responsibilities across the continuum of care may find it increasingly difficult to justify their presence in healthcare institutions.

These systems are critical tools for the effective delivery of pharmaceutical care as healthcare grows more complex. The pharmacy must advocate for a leadership role and provide its expertise in systems and medication therapy to ensure the success of the medication component of CPOE with CDS.³⁶ It is essential that pharmacists share their experience with colleagues and advocate for standardization to enhance the successful diffusion of this powerful tool. CPOE provides new opportunities for pharmacists in the area of system integration and CDSSs and demands that more formalized training for pharmacists be available. A good CPOE system that is properly deployed provides strategic advantages to the institution and, most importantly, improved care to patients.

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CHAPTER REVIEW QUESTIONS

1. **A personal health record (PHR) can contain computerized clinical documentation of a patient's medical care over time within only a single institution.**
- a. True
 - b. False

Answer: b. False. A PHR is a web-based platform accessible to and controlled by patients about their own medical care and insurance coverage that may be available to multiple institutions.

2. **A passive CDS intervention in CPOE systems presents relevant patient-specific recommendations to the prescriber by interrupting their workflow.**
- a. True
 - b. False

Answer: b. False. Passive CDS interventions are generally unobtrusive, whereas active alerts can be noninterruptive or interruptive in how they are presented to the user.

3. **CPOE has been widely adopted and implemented in U.S. hospitals.**
- a. True
 - b. False

Answer: b. True. CPOE for medications has become widespread across the United States in more than 80.9% of hospitals as the Meaningful Use initiative incentivized adoption and use.

4. **Why does the CPOE system implementation have a significant impact on the pharmacy?**
- a. Complexity of processing medication orders
 - b. Necessity of content management for medication-related decision support
 - c. Volume of transactions associated with medication orders
 - d. All of the above

Answer: d. All of the above. Medications constitute a significant portion of the physician orders often triggering medication-related decision support.

5. _____ is a program introduced through the U.S. Health Information Technology for Economic and Clinical Health (HITECH) Act, to financially incentivize healthcare providers to use EHRs.
- a. HIPAA
 - b. Joint Commission
 - c. Meaningful Use
 - d. Institute of Medicine

Answer: c. Meaningful Use. It incentivized healthcare providers to use EHRs.

6. **The following term describes the capability of different information systems to exchange and use data.**
- a. Interoperability
 - b. Data standardization
 - c. Functionality
 - d. None of the above

Answer: a. Interoperability. Data standardization defines the terminology and formatting of data to be consistently entered into EHRs. Functionality refers to all of the things (i.e., functions) that a software program or system can do for users.

7. Consolidated-Clinical Document Architecture (C-CDA) is a standard for clinical data sharing, and it is a meaningful use certification requirement for EHR systems.

- a. True
- b. False

Answer: a. True. C-CDA defines the structure of certain medical records to improve data sharing among healthcare organizations. It is a meaningful use certification requirement for EHR systems.

8. Which of the following organizations support CPOE adoption?

- a. Centers for Medicare & Medicaid Services (CMS)
- b. U.S. Department of Health and Human Services (HHS)
- c. Institute of Medicine (IOM)
- d. Office of the National Coordinator (ONC)
- e. All of the above

Answer: e. All of these governmental and private organizations support CPOE.

9. CPOE and e-prescribing are synonymous terms.

- a. True
- b. False

Answer: b. False. CPOE describes orders entered electronically anywhere within a health system's EHR. Electronic prescribing, or e-prescribing, refers only to CPOE in ambulatory care settings.

10. There are four possible outcomes for any alert associated with CDS. Which of the following puts patients at greatest risk?

- a. Alert for clinically significant problem
- b. No alert generated because of no problem
- c. Alert generated for a clinically insignificant problem
- d. No alert generated for a clinically significant problem

Answer: d. Not being aware of clinically significant problems puts patients at greatest risk (see Table 10-1). However, an argument can be made that alerts generated for clinically insignificant problems can desensitize the clinician to clinically appropriate alerts and put the patient at equal risk.

CHAPTER DISCUSSION QUESTIONS

1. Why is it so difficult to exchange patient data among different healthcare organizations?
2. Under what conditions should a pharmacist override clinical decision support alerts?
3. Will CPOE ever preclude a need for pharmacists? Why?
4. Is it possible to practice clinical pharmacy without access to the medical record electronically or in paper form? Why?

Automation in Practice

Brad Ludwig and Jack Temple

LEARNING OBJECTIVES

After completing this chapter, readers should be able to:

1. Describe how technology and automation can increase safety and efficiency within the medication-use system.
2. Identify the limitations of existing automation in the medication-use system and the impact of automation on the delivery of patient care.
3. Define key terms in pharmacy automation.
4. Review the role of regulations, standards, and guidelines in use of technology and automation.
5. Discuss required financial, personnel, and facility resources as they relate to the safe use of technology and automation.

KEY TERMS AND DEFINITIONS

- **Automation:** Any technology, machine, or device linked to or controlled by a computer and used to do work.
- **Bar-coded medication administration (BCMA):** A process that encompasses the use of bar-code scanning functionality into the medication administration phase of medication use and combines a number of hardware and software components to display, receive, and chart real-time patient and medication information.
- **Carousel dispensing technology (CDT):** A medication storage cabinet with rotating shelves used to automate medication dispensing.
- **Computerized provider order entry (CPOE):** A computer application that allows providers to type prescriptions into a computer and send them directly to the pharmacy (instead of using orders sheets or prescription pads). Also known as computerized physician order entry (CPOE) and prescriber order entry (POE).
- **Decentralized automated dispensing devices:** Secure storage cabinets capable of handling most unit dose and some bulk (multiple-dose) medications. Also known as automated dispensing cabinets (ADCs), automated dispensing machines (ADMs), automated dispensing units (ADUs), and unit-based cabinets (UBCs).
- **Electronic medication administration record (eMAR):** A real-time, computer displayed medication administration record.
- **Human factors engineering:** The discipline of designing workplace facilities and tasks to meet the needs and optimize the performance of human beings.
- **Integrate:** A process in which separate components or subsystems are combined or designed together, at the same time, with a unifying architecture and with problems in their interactions being addressed.

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- **Interface:** A physical or electronic connection that enables otherwise incompatible computer systems to communicate and exchange data.
- **Medication-use process:** A multistep process consisting of five domains: (1) prescribing/medication determination; (2) medication preparation, dispensing, and counseling; (3) medication administration; (4) patient monitoring/assessment; and (5) purchasing/inventory management.
- **Radio frequency (RF) network:** Commonly used in the wireless communications industry to describe equipment using radio frequency waves to transmit sounds and data from one point to another.
- **Robotics:** Mechanical devices that perform programmed, complex, and repetitive manipulations without continuous input from an operator.
- **Smart pumps:** Infusion devices with clinical decision support software and drug libraries that perform a test of reasonableness at the point of medication administration.
- **Supply chain management:** Oversight of the process of moving products, information, and money among pharmacies, wholesalers, pharmaceutical companies, and other organizations in the supply chain.
- **Technology:** Anything that is used to replace routine or repetitive tasks previously performed by people, or which extends the capability of people.



INTRODUCTION

Technological advancements are a constant in today's healthcare marketplace where payers and patients demand high-quality, efficient, and cost-effective service. **Technology**, which is defined as anything used to replace routine or repetitive tasks previously performed by people or to extend the capability of people, is a prerequisite to the survival of the profession and the advancement of pharmacist patient care services.

Automation is a form of technology. **Automation** is defined as any machine or device linked to or controlled by a computer and used to do work. Thus, all automation is a form of technology but not all technology is automation. Automation can be considered **robotic** if it operates autonomously.

This chapter provides an introduction on the use of automation in inpatient pharmacy practice. It discusses best practices for maximizing the safe and efficient use of automation and describes how automation might impact the future of pharmacy practice. This chapter is not a comprehensive review of all available automated devices and technologies; it only briefly mentions automation associated with **computerized provider order entry (CPOE)** and clinical decision support (CDS) systems. Those forms of technology are discussed in more detail in Chapter 9, Informatics, and Chapter 10, Electronic Data Management.

KEY POINT...

All automation is a form of technology, but not all technology is automation.

... SO WHAT?

In conversations, technology and automation are often used interchangeably, but they are different. Automation is a subset of technology. It is specific only to technology controlled by computers that are used to do work.

HISTORY

The application of automation within the practice of pharmacy began in the early 1960s, although the pace has increased dramatically in the last 20 years. Improved technology, the need to control costs of care, and a demand for safer patient care have driven the recent demand for automation, which helps pharmacy managers do more with less (i.e., provide better, faster service with fewer employees) and free pharmacists to provide patient care services to improve health outcomes.

Wholesalers have been critical to the growth of automation in many health-system pharmacies. Wholesalers are intermediary businesses that purchase pharmaceuticals from drug manufacturers for resale to pharmacies. Since the mid-1990s, major wholesalers (Amerisource Bergen, Cardinal Health, and McKesson) expanded their technology support services for health-system pharmacies by partnering with or buying pharmacy technology and automation companies. Wholesalers offered a range of products and support services including hand-held bar-code scanners, inventory control systems, and automated dispensing devices. Pharmacies partnered with wholesalers because they typically did not have the expertise, personnel, or time required to automate without assistance.

During the early to mid-2000s, innovative software and hard platforms flooded the market from private/public companies. These innovations filled niche gaps that resulted from the wholesalers' purchase of automation vendors. The rapid introductions of innovations were a direct result of the expansion of Internet, WiFi, smart devices, and cloud-based platforms. In recent years, the automation vendor market has continued to evolve with some wholesalers spinning off their automation subsidiaries. Some of these spinoffs have become independent companies, while others have merged with competitors to hold onto or consolidate market share.

AUTOMATION AND PATIENT SAFETY

Automation can help improve the safety of the medication-use system. Bates et al. described four phases in the **medication-use process**: ordering, transcribing, dispensing, and administration, where potential and preventable adverse drug events (ADEs) could be found.¹ They found that 49% of all preventable and potential ADEs occurred in the ordering phase and 26% in the administration phase. When only medication errors causing patient harm were considered (i.e., preventable ADEs), 90% of preventable ADEs occurred during the ordering and administration phases of the medication-use process.

The data suggest that technology, along with automated systems aimed at improving ordering and administration in the medication-use process, can have the greatest impact on patient safety in hospitals. Electronic health records (EHRs) and the use of CDS-based CPOE systems can assist the ordering phase by guiding prescribers through the order entry process and reduce the need to transcribe orders. **Bar-coded medication administration (BCMA)** technology helps improve the administration phase by ensuring the five rights of medication administration: right patient, right medication, right dose, right time, and right route. Other technologies are currently in use in many health systems within various components of the medication-use process. **Table 11-1** provides a list of these technologies.

DRUG PURCHASING AND SUPPLY CHAIN MANAGEMENT SYSTEMS

Automating the ordering process between suppliers and the pharmacy can improve the drug purchasing, inventory control, and other tasks in **supply chain management**.^{2,3} Purchasing and inventory control systems automation can help simplify the medication procurement

TABLE 11-1.
Technologies and Automated Devices Applied throughout the Medication-Use Process

Prescribing

- Clinical decision support software
- Computerized provider order entry

Dispensing

- Carousel technology
- Centralized robotic dispensing technology
- Centralized narcotic dispensing and inventory tracking devices
- Decentralized automated dispensing devices
- IV and total parenteral nutrition compounding devices
- Pneumatic tube delivery systems
- Unit dose medication repacking systems
- Robotic delivery technology
- Robotic IV/chemotherapy preparation technology
- IV compounding workflow software
- Medication tracking software

Administration

- Bar-coded medication administration technology
- Clinical decision support-based infusion pumps

Monitoring

- Electronic clinical documentation systems
- Web-based compliance and disease management tracking systems

IV: intravenous

(ordering) and receiving process, reduce on-hand drug product inventory, and lower product acquisition costs. Using hand-held product reordering devices to scan bar-coded product shelf labels in inventory management is an example of one technology used in supply chain management.

To develop an efficient supply chain management program, it is common for health-system pharmacies to partner with a pharmaceutical wholesaler. The largest wholesalers use state-of-the-art inventory management technology, employing sophisticated computer programs to manage and track orders and deliveries, bar codes and radio frequency signals to monitor products

KEY POINT . . .

Automation systems aimed at improving ordering and administration in the medication-use process can have the greatest impact on patient safety in hospitals.

. . . SO WHAT?

Most preventable errors occur in ordering and administering drugs, so efforts in these areas are more likely to bear fruit. Many steps in ordering and administration can be automated, thereby providing further justification for automated systems that can improve patient safety.

moving through the supply chain, and robotics or other forms of technology not typically available to hospital pharmacies. Along with their investment in inventory management, wholesalers have increased their web presence by expanding their use of web-based portals for ordering, receiving, and the storage/exchange of supply chain information. Many of these portals operate off a standard data structure. For example, if a pharmacy's computer order processing system can maintain an accurate perpetual (i.e., continually up-to-date) inventory of products on the shelf and account for all dispensing and crediting transactions, that system also may be able to electronically communicate real-time inventory levels to the wholesaler's order management system and automatically place an order to the wholesaler when inventory levels fall below a predetermined quantity. Such a system works best with dispensing technology that maintains a closed perpetual inventory record of drug products. When products are received in the pharmacy from the wholesaler, the same **interface** permits new inventory quantities received to be added to the EHR's or automated dispensing technology's perpetual inventory.

Some wholesalers provide pharmacies with hand-held scanning devices with integrated bar-code readers to automate the procurement process. Use of the scanners provides an automated receiving and invoice reconciliation process, thus automating the labor-intensive and error-prone product check-in process. The process begins when a pharmacy technician scans a bar code on a delivery tote (i.e., container) from the wholesaler, which in turn generates an electronic invoice. Each product bar code is then scanned as it is removed from the tote, and the products received are electronically reconciled against the invoice. The system automatically credits product invoicing discrepancies, arranges for miss-picks (shipping errors) to be returned, and updates the pharmacy's perpetual inventory for products received. This same scanner can be used to generate new orders to send to the wholesaler and generate return requests to the wholesaler for damaged or unused products. After products are received, payments can be sent from accounts payable to the wholesaler via the Internet.

Some hospitals have partnered with wholesalers to implement automated procurement systems for supplies of medications such as those maintained in an automated dispensing technology or in a pharmacy stockroom. Others have merged with multihospital health systems to automate their supply chain management. One key goal of automating the supply chain is *inventory visibility*, which is the ability to have immediate access to accurate inventory figures at each stage of the supply chain. This can lead to long-term savings and efficiency by maximizing drug inventory turn rates, avoiding expired inventory, and reducing labor required for the drug procurement process.

A final area of emerging technology in the pharmaceutical supply chain are software platforms that aid pharmacies in compliance with the Drug Quality and Security Act (DQSA) signed into law in 2013. Title II of the DQSA, Drug Supply Chain and Security Act (DSCSA), set forth provisions related to electronic tracking of each pharmaceutical purchase, sale, and product return to detect and reduce counterfeit products that may have entered the pharmaceutical supply chain.

The law requires an electronic tracking document for each product exchange, referred to as the T3, which stands for transaction information, transaction history, and transaction statement. Pharmacies are required to receive and keep T3 documents for 6 years for transacted products. Software platforms have been developed to manage and update T3 documentation.

DRUG DISTRIBUTION AND DISPENSING SYSTEMS

Automation is widespread throughout the drug dispensing and filling process. This section briefly describes how technologies can help improve the safety of the medication-use process. Only a sampling of technologies is discussed. More detailed discussions on the topic can be found elsewhere in the literature.⁴⁻⁷

Decentralized Automated Dispensing Devices

As discussed in Chapter 7, Medication Distribution Systems, **decentralized automated dispensing devices** are secure storage cabinets capable of handling most unit dose and some bulk (multiple-dose) medications. The devices are also referred to as *automated dispensing cabinets (ADCs)*, *automated dispensing machines (ADM)*s, *automated dispensing units (ADUs)*, and *unit-based cabinets (UBCs)*. Automated dispensing devices store and electronically dispense medications in locations remote from a centralized or satellite pharmacy. They allow nurses immediate access to medications at the point of use without requiring a visit to a pharmacy. At the same time, pharmacists can control drug use by requiring nurses to access the machines with user identifiers and passwords. Summarized dispensing reports can also help hospitals to monitor for diversion and to bill patients.

Automated dispensing devices were originally installed in hospitals in the early 1990s to provide increased control over controlled substances and floor stock medications in patient care areas. By 2014, approximately 97% of U.S. hospitals were incorporating decentralized automated dispensing devices. This has increased from 49% in 1999, 83% in 2008, and 89% in 2011.⁸

The primary focus of these automated dispensing devices is to provide prompt, real-time availability of medications for the nurse and patient. They can also help to improve controlled substance accountability, increase productivity, improve charge capture and documentation accuracy, and reduce pharmacy and nursing labor costs. Many hospitals now use these devices to store and dispense nearly all scheduled doses, thereby eliminating the manual medication cart fill and delivery process. However, the impact of these decentralized automated dispensing devices on medication errors is less clear.^{9,10}

Automated dispensing devices can improve safety by incorporating bar-code labeling and scanning into the replenishment process, thus improving restocking accuracy and potentially improving medication safety. Also, safety can be improved if automated dispensing devices free pharmacists to direct patient care activities, including medication therapy management services.

However, automated dispensing devices can introduce medication errors if not implemented and/or managed appropriately. Some devices allow nurses to access any patient and dispense any drug they choose. This may permit the selection of inappropriate medications for administration, diversion of medications for personal use, or inadequate documentation of what drugs were administered to which patient. Problems can also occur when some nursing units have automated dispensing devices, while others have manual cart fill. Mixed systems like this can cause problems as patients are moved between units and may preclude an institution's ability to maintain a well-controlled, single-dose medication dispensing system. In addition, some health systems have yet to link their EHRs to cabinets in a way that restricts nurses from obtaining medications that are not ordered for patients. Other safety concerns include:

1. Retrieving of an incorrect medication because of open access to all drugs in a drawer.

2. Carelessness or lack of verification of drug labels due to a belief that the system is computerized and, therefore, not as susceptible to errors (or the belief that pharmacy placed the drug there and pharmacy does not make mistakes).
3. Drugs stocked in the wrong pocket either because one or more doses inadvertently fell into the wrong slot or due to a pharmacy restocking error.
4. Changing of the location of the drug in the cabinet, which can cause errors because drugs may be selected from particular locations based on habit rather than verifying each drug's identity.¹¹

Conflicting reports exist in the literature on the impact of automated dispensing devices on medication error rates and provider efficiency.¹¹⁻¹⁴ Unfortunately, significant capital investments have been made in these systems without full understanding of their impact on operations and patient safety. Therefore, it is important for pharmacists to involve themselves in understanding the procurement, implementation, and efficient use of these systems. One way is to become familiar with the Institute for Safe Medication Practices (ISMP) interdisciplinary guidelines to help ensure the safe use of decentralized dispensing devices.¹⁵ The guidelines were developed around 12 core processes and list approximately 100 different principles for the safe and effective use of the decentralized automated dispensing devices. **Table 11-2** lists guidelines and considerations for the safe use of decentralized automated dispensing devices. **Table 11-3** compares potential advantages and disadvantages of decentralized automated dispensing devices.

KEY POINT . . .

Automated dispensing devices can introduce medication errors if not implemented and/or managed appropriately.

. . . SO WHAT?

Sometimes, there is a tendency to rely too much on technology. Automated dispensing devices and other technology are not perfect, nor are the individuals using them.

Over-reliance on technology can lead pharmacy employees to be less vigilant to potential risks to patients. Pharmacists need to implement and manage processes that take into account the various ways that errors can arise with technology.

Automation in Centralized Dispensing

Centrally located dispensing devices help automate the entire process of medication dispensing from a pharmacy. As previously discussed in Chapter 7, Medication Distribution Systems, the rise in the use of technology for medication dispensing can replace many of the manual tasks for medication dispensing and reduce the number of pharmacy staff needed for the process. In the past, most centralized robotic systems were used to select bar-coded unit dose medications for scheduled medication cart filling, and such devices were interfaced with the EHR to provide access to each patient's medication profile. Today, centralized robotics are also used to automate first-dose dispensing and to replenish low stock medications in decentralized automated dispensing devices. Thus, as long as the patient's medication profile in the EHR is maintained in an accurate and timely manner, the pharmacist's time spent checking medications may be reallocated to more direct patient care activities.

Perhaps one of the greatest advantages of implementing robotic technology is that all robot-dispensed doses are bar-coded, thus providing a foundation for the implementation of a BCMA system. Bar coding of medication doses allows dispensing accuracy to approach 100% with centralized robotics technology. However, this necessity for bar codes on all robot-dispensed medications has the potential to introduce new errors into the medica-

TABLE 11-2.
Guidelines for Safe Use of Decentralized Automated Dispensing Devices

- Assign medications to devices based on the needs of the patient care unit, patient age, diagnosis, and staff expertise.
- Create an alert system to flag high-risk medications stocked in devices (e.g., a maximum dose prompt).
- Develop an ongoing competency assessment program for all personnel with access to the device and include direct observations and random restocking accuracy audits; observe dispensing accuracy as part of the assessment.
- Develop a system to locate and remove recalled and expired medications.
- Develop clear, multidisciplinary downtime procedures; include procedures in training and ongoing competency programs.
- Develop systems to account for narcotic waste; routinely audit controlled substance dispense quantities against patient orders, medication administration record documentation, and waste documentation.
- Display allergy reminders for specific drugs such as antibiotics, opiates, and nonsteroidal anti-inflammatory drugs (NSAIDs) on appropriate medication storage pockets or have them automatically appear on the dispensing screen.
- Do not allow nurses to return medications to the original storage pockets/locations; assign a return bin to collect returned medications.
- Establish a preventive maintenance schedule with the vendor that does not disrupt workflow.
- Establish strict security criteria to limit unauthorized access to devices.
- Establish stringent safety criteria for selecting medications that are (and are not) appropriate to store in devices and oversee the process for assigning new drugs to new locations in all care settings.
- Incorporate bar-code scanning for restocking and medication retrieval.
- Limit the numbers of medications not available in profile dispense that may be overridden (dispensed without pharmacist review and verification).
- Maximize the use of unit dose medications in ready-to-administer form, with only a few exceptions.
- Only assign medications with minimal harm potential to open access drawers.
- Perform routine expiration date checks as well as concomitantly verifying inventory quantities.
- Require all personnel to attend formal training and demonstrate competency prior to accessing the devices.
- Require pharmacist medication order review and verification before a medication is accessed for first-dose administration (profile dispensing).
- Restrict access to provide single dose (or single drug) availability whenever possible; focus control on high-risk medications and controlled substances (pocked-lidded pockets).
- Separate sound-alike and look-alike medications; do not stock these medications in the same open-access drawer.

tion-use system. Although some manufacturers provide bar-coded medications to use in centralized robotic devices, the pharmacy department must accurately repackage most unit dose medications with a bar-coded label. A disadvantage for centralized robotic devices is the increase in labor needed to repackage medications. To offset the repackaging requirement, many technology companies have developed automated packagers and even full service agreements alongside robotic devices to assist with the labor-intensive packaging requirement. Overall, the use of robotics for centralized dispensing can reduce pharmacy labor costs, eliminate routine and repetitive tasks associated with dispensing, and improve medication dispensing accuracy.

Carousel dispensing technology (CDT) is a dispensing device that consists of a medication storage cabinet with rotating shelves and comprehensive software that manages inventory and prioritizes workflow. Like other dispensing technologies, CDT utilizes bar-code scanning technology to improve the efficiency and accuracy of pharmacy technicians who pick and restock medications. Likewise, the carousel must be interfaced with the EHR to achieve maximum benefits for safety and efficiency.¹⁶⁻¹⁸ It can reduce technician travel time, bending, and reaching for medications during the filling process. Rotating shelves within the carousel place medications at easy-to-reach levels with a light identifying the exact location. The rotating shelves maximize rarely used vertical space to store medications. In addition, medications do not need to be stored alphabetically, so they can be arranged in any order to help increase dispensing efficiency and meet regulatory requirements for dispensing high-alert, sound-alike, and look-alike medications. Finally, CDT systems can be integrated or interfaced with decentralized UDCs to coordinate dispensing activities within the medication-use system.

TABLE 11-3.

Potential Advantages and Disadvantages of Decentralized Automated Dispensing Devices

Advantages	Disadvantages
<ul style="list-style-type: none"> ■ Adds extra cabinets to increase capacity. ■ Restricts access to a single dose of a medication. ■ Has flexible drawer configurations that accommodate multiple types of dosage forms. ■ Helps resolve discrepancies by automating controlled substance retrieval and inventory reconciliation. ■ Automatically charges patients for drugs used. ■ Has bar-code scanning integral to system. ■ Reduces the time needed for patients to receive their first dose. ■ Improves nursing satisfaction due to fewer missing doses, fewer delays for first doses, and more nursing control over day-to-day medication distribution activities. ■ Enables more pharmacy control versus traditional floor stock system. ■ Provides detailed electronic dispensing and usage reports. ■ Frees pharmacists to perform patient care activities. ■ Saves nursing labor. ■ Eliminates problem of missing or misplaced narcotic drawer keys. ■ Eliminates narcotic counts at shift change. ■ Requires fewer narcotic discrepancies to resolve. ■ Reduces narcotic paperwork to handle. 	<ul style="list-style-type: none"> ■ Accurate inventory quantities may be difficult with mixed distribution systems (automated and nonautomated). ■ Automation breakdowns may impact patient care. ■ Duplicate inventory in large numbers of dispensing cabinets may increase inventory costs and the amount of expired medications. ■ If devices are used to replace cart fill, several devices are needed per nursing unit. ■ Inspection and removal of expired medications must be performed manually (devices do not have the software to track expiration dates). ■ Multiple-dose access is still common in systems, allowing for diversion and misuse. ■ There is poor integration with bedside medication storage systems. ■ Potential labor cost savings are frequently not realized. ■ There is potential for nurses and pharmacists to take shortcuts around the system, leading to errors. ■ They are unable to accommodate all medications (limited by medication size, cabinet size, and risk level for a particular medication to be stocked in a device).

Narcotic Dispensing and Record-Keeping Systems

As described in Chapter 8, the management of controlled substances is one of the most labor-intensive processes in health-system pharmacy. Automation helps manage the ordering, storage, dispensing, and administration of all controlled substances from the wholesaler to the nursing unit. Such systems record all doses dispensed from a central pharmacy narcotic room by scanning manufacturers' bar codes, and provides a record of the individual performing every transaction. Additionally, they can be stand-alone or interfaced with decentralized automated dispensing devices to verify that every dose dispensed from the pharmacy is stocked in the intended decentralized automated dispensing device. They generate bar-coded tracking forms for nurses to maintain accurate inventory accounting on units without automated dispensing devices and suggest reorder quantities based on past controlled substance use. Lastly, they help provide compliance and controlled substance disposal reports for the Drug Enforcement Administration. The key benefits for using automated narcotic dispensing and record-keeping systems include accurate record keeping, enhanced control of narcotics, improved regulatory compliance, and efficient ordering processes. In addition to tightening up the security of controlled substances, automated systems can help identify potential drug product diversion. Thus, it is very common to find hospitals that have moved all traditional, narcotic vault drug inventories into ADCs linked to narcotic inventory control software.

STERILE COMPOUNDING ROBOTS AND WORKFLOW SOFTWARE

Robotic systems are used in sterile preparation of syringes and intravenous (IV) bags. Robots are precisely calibrated to meet specific tolerances, such as how deeply to insert a needle into the injection port of an IV bag. Accuracy of robotic compounding is assured through double-checks during preparation and the use of bar-code scanning and image recognition technologies. Pharmacists verify each dose either on site or remotely by examining medication images at a remote computer work station linked to the IV workflow system.

Robots are more efficient when producing large batches of medications. The setup and preparation time for preparing single doses or small batches may be greater for robotic preparation when compared with a trained technician.

When used in preparing large numbers of sterile products, IV robots can increase compounding accuracy and reduce errors. They can also reduce staff exposure to hazardous medications by taking them out of the manual process of IV sterile product preparation. They may also extend beyond-use dating as sterile compounding is done in closed environments maintaining ISO 5 air quality throughout the compounding process.

Although IV robotic technology is promising, it has limitations. Caution is advised when using it to extend beyond-use dating because USP Chapters 797 and 800 are not clear on this subject. Furthermore, exposure of employees to hazardous medications can occur because some systems still require manual manipulation of the product (e.g., capping syringes). Costs of preparation can also increase because many systems require the purchase of supplies (e.g., needles, syringes, IV bags) that are specific to the IV robots and not available for use in other systems. Finally, many types of sterile products cannot or should not be prepared using robotic technology, so there will always be a need for the manual IV medication preparation.

In addition to robotic sterile preparation, technology can facilitate manual compounding. IV room workflow software systems aid in manual preparation by receiving orders written into the EHR and populating the orders into a workflow queue for technicians to prioritize the preparation of doses. The software generates a compounding label and allows medications to be verified via either a bar-code scan or gravimetric check. Images are captured for all relevant steps in the compounding process to allow pharmacists to verify each step for

accuracy. The pharmacist is able to complete this verification process onsite or remotely from any workstation with access to the IV workflow system.¹⁹⁻²²

MEDICATION DRUG ADMINISTRATION SYSTEMS

eMAR with BCMA Technology

BCMA or bar-coded medication administration is a process that incorporates the use of bar codes into the medication administration phase of medication use. It utilizes a number of hardware and software components to display, receive, and chart real-time patient and medication information, providing caregivers (usually nurses) with the information needed to accurately administer and document the medications given to patients. BCMA consists of a three-way check of the nurse, medication, and patient at the bedside, whereby the technology checks scanned bar codes on the nurse's identification badge, the dose of medication, and the patient's identification wristband. It also verifies the drug against the patient's **electronic medication administration record (eMAR)**, documents the time and details of administration, and can generate a charge for the drug to the billing department. If a medication is not given, the eMAR system requires the nurse to document the reason. BCMA helps to ensure the five rights of medication administration: right patient, right medication, right dose, right time, and right route.

BCMA facilitates real-time updates to the eMAR, enabling all caregivers to view updated information about the patient's current and past medication regimens and make judgments about future medication administrations. Many systems use hand-held laser bar-code scanners tethered to a computer or mobile, wireless, hand-held smart devices linked to the EHR via a **radio frequency (RF) network**. For all scheduled doses, the EHR, eMAR, or smart device alerts the nurse when it is time to administer the medication.

This technology can dramatically reduce drug administration errors.^{23,24} Organizations that have implemented this technology report up to 87% reductions in medication administration errors, with up to 10% of doses scanned preventing at least one of the following discrepancies: wrong patient, wrong drug, wrong dose, or wrong time.^{24,25}

Although improvements are being made in BCMA and other eMAR technology, effectively implementing these systems can be costly and complicated. Major limitations to implementing BCMA include:

- The cost of the BCMA software.
- The cost of BCMA-related hardware such as portable scanning devices, bedside computers, centralized computer servers, bar-code printing systems for patient and caregiver identification tags, and bar-code medication repackaging systems.
- All medications must be bar coded in unit-of-use packaging to achieve the optimal safety benefit, usually requiring labor-intensive and potentially error-prone repackaging in the pharmacy.
- The need to redesign nursing workflow.

KEY POINT . . .

BCMA helps to ensure the five rights of medication administration: right patient, right medication, right dose, right time, and right route.

. . . SO WHAT?

BCMA technology can be used to verify the patient via a wrist band; the medication, dose, and route via a bar code on the package; and the time via a built-in chronometer. Things can still go wrong, but BCMA technology can significantly prevent medication errors.

Because one of the major limitations of BCMA technology is the need to bar code all medications, a cursory understanding of the information contained in a bar code is necessary. A *bar code* is simply a graphic representation of data (alpha, numeric, or both) that is machine-readable. Bar codes are a way of encoding information using a combination of bars and spaces of varying widths stacked side by side. The scanner reads and interprets the rows and spaces as data. Data on medication bar codes can include information about the drug's name, dose, dosage form, route, expiration date, and lot number. Bar codes come in many varieties and symbologies (i.e., bar code languages). A scanner's ability to quickly and accurately interpret bar-code data depends on the quality of the bar-code print on the product as well as the symbology and configuration of the bar code. Because space available on most unit dose packages is limited, bar coding these packages is difficult although many manufacturers have been very successful in doing so.

Many pharmacies have to repackage and bar-code medications because some packages from manufacturers do not have usable bar codes. Unit dose packaging machines that have bar-coding capabilities can be purchased or leased. The cost to purchase can be substantial to prepare all the needed dosage forms, but acceptable when weighed against the benefits in patient safety and added efficiency. Pharmacies can reliably and efficiently bar code virtually all medication forms including solids, liquid cups, vials, ampules, and syringes. Much literature exists on the successful development and implementation of pharmacy-based bar-code packaging operations and distribution systems.²⁶

BCMA, by itself, is not an all-encompassing solution for medication safety. With any new process, there exists the potential for new sources of error including pharmacy medication repackaging errors, software failures, inefficient and inaccurate display of medication order information on the BCMA screen, and nursing workarounds (i.e., short cuts that subvert the safety system). In many pharmacies, individuals must be dedicated to dealing with the problems encountered in BCMA technology. This additional cost is unavoidable given the potential benefits of BCMA. **Table 11-4** provides a list of trade-offs associated with BCMA systems.

Clinical Decision Support–Based Infusion Pumps

CDS-based infusion pumps can reduce errors associated with the administration of medications through less sophisticated IV infusion pumps. Variations in IV medication practices are associated with increased risk of patient harm,²⁷ and as many as 60% of serious and life-threatening errors may be associated with problems with IV therapy.²⁸

IV infusion technology has become increasingly sophisticated over the years. **Smart pumps** (computerized infusion pumps) can now be programmed to infuse several medications simultaneously and assist with complex dose calculations (i.e., loading, bolus, and maintenance doses). Devices can signal alerts when air is detected within the infusion line and be dedicated for specific needs (i.e., patient-controlled analgesia, epidural pumps). Smart pumps can also perform clinical decision support at the point of care. This means a nurse can program a pump at the bedside, and it will automatically check if the programmed doses are within acceptable ranges established by the pump's drug library. Doses outside acceptable ranges trigger an alert that must be addressed before the infusion can begin.

KEY POINT . . .

Smart pumps take IV medication infusion safety a step further by performing CDS at the point of care.

. . . SO WHAT?

Point-of-care technology allows professionals to adapt to the immediate situation at hand. Decisions can be made in response to patient needs at the bedside.

TABLE 11-4.

Potential Advantages and Disadvantages of eMAR with BCMA Technology

Advantages	Disadvantages
<p>Automated documentation</p> <ul style="list-style-type: none"> ■ Comprehensive data and reports available on demand ■ Ability to facilitate precise pharmacokinetic monitoring ■ On-demand view of a patient's history of administered medications ■ Ability to record and verify in real time the exact time of medication administration information (eliminates missed/incomplete documentation) <p>Improved patient safety and accuracy</p> <ul style="list-style-type: none"> ■ Allergy checks are performed at the bedside ■ Bar-code scanning to verify the appropriateness of a medication at the patient's bedside ■ Appropriate packaging and labeling of unit dose medications up to the point of administration, at the patient's bedside ■ Nurse is immediately alerted to discrepancies (wrong drug, dose) ■ Nurse is immediately alerted to missed doses ■ Real-time order and patient information is available to the nurse at the bedside <p>Increased charge accuracy through automation</p> <p>Automated tracking for controlled substances removed from decentralized dispensing devices but never scanned</p> <p>Marketing tool for the organization</p> <p>Nursing convenience</p> <ul style="list-style-type: none"> ■ Customizable, medication administration planning reports ■ Easy documentation of medication administration criteria and vital signs at the bedside ■ MAR is mobile and paperless ■ Small, lightweight, wireless hand-held devices 	<ul style="list-style-type: none"> ■ A number of devices are needed for busy or large nursing units; this may be cost-prohibitive for some organizations ■ All medications must be bar coded to ensure a realization of the safety benefits shown ■ Lack of standard bar codes in health-care ■ Manual printing of patient MARs at discharge for an organization without a fully integrated or interfaced electronic medical record ■ Possible competition among nurses for access to devices (dependent on number of devices an organization can afford) ■ RF demands may be problematic for some organizations ■ RF devices are required for real-time updates from EHR system; may interfere with clinical patient monitoring devices ■ Short battery life requires extra batteries or frequent battery exchanges ■ Success is dependent on nursing acceptance of the change <ul style="list-style-type: none"> ● Implementation causes dramatic changes in how nurses perform their job

EHR: electronic health record; eMAR: electronic medication administration record; RF, radio frequency.

Smart pump software allows institutions to create individualized hospital profiles and drug libraries. Hospital profiles provide specific infusion device operating parameters, programming options, and drug libraries for specific patient populations (i.e., pediatric, pediatric intensive care, neonatal intensive care, adult critical care, or adult general care). Drug libraries are often institutional-specific medication lists that contain standard concentrations and preset dosing limits. Institutions often have the option to make dosing limits either hard limits (alerts that cannot be overridden) or soft limits (an overrideable alert with action). Once the pump is programmed, the smart pump software performs a test

of reasonableness against the hospital profile and the drug library to verify the pump has been programmed correctly for the specific patient population and medication.

Smart pump software also has event recording capabilities. Data logs can track events such as the number of infusions programmed, the number of times an alert is given, the number of times an alert is overridden, and detailed records for programming errors that were averted and could have caused patient harm. Depending on the vendor selected, data logs can often be accessed through direct or RF downloads from each pump to a computer.

Dramatic reductions in medication infusion error rates can be seen with smart pump implementation.^{29,30} However, smart pump technology is by no means foolproof, and at least one study found no measurable impact on the serious medication error rate following smart pump implementation, likely in part due to poor compliance.³¹ Clinicians still have to use their own judgment. Workarounds circumventing the desired safety features of these pumps are common as the design of these pumps makes it easy for nurses to bypass the drug library that contains the drug dosing and rate limits. Alert fatigue is also a consideration if nurses are routinely prompted with alerts that are not considered clinically significant. Convincing nurses to use the safety features of this technology during time-pressed situations can be a challenge.

Smart pump vendors are developing smart pumps that are electronically linked to EHRs. Advances in these pumps are slow due to difficulties accounting for all the complex dosing and decision points for administering infusion therapies (dose, rate, titration parameters). As these pumps evolve, nurses will no longer need to manually select medications or manually program the pump at the bedside. An electronic link between the EHR and smart pump can also allow pharmacists to review medication orders with smart pump parameters and aid in the accurate documentation of infusion therapy in the medical record. Dose titrations and volumes of medications infused can be read from the EHR and help ensure quick initiation of therapy and dosing changes. Pharmacy departments can also take advantage of developing EHR and smart pump **integration**. Integration can allow smart pumps and EHRs to exchange information near real-time. Pharmacists will be able to monitor infusion therapies and ensure timely dispensing to patients' bedsides without relying on a notification from the nurse or requiring pharmacy staff to perform medication infusion rounds (determining when the next infusion is needed).

Given that IV medication errors and ADEs are common and often very harmful, the use of this technology is likely to expand rapidly, perhaps more rapidly than BCMA and CPOE software. Although it has great promise, technological and nursing behavioral factors must be effectively addressed if smart pumps are to achieve their potential for improving medication safety.

Pharmacists must be very involved in the smart pump selection and implementation, particularly in developing the drug library and programming processes. They also need to be involved with alert analysis, quality assurance, and drug library upkeep. This technology offers a tremendous opportunity for pharmacist leadership in health systems.

SAFETY ISSUES SURROUNDING THE USE OF AUTOMATION

Ensuring System Accuracy and Reducing Errors

Although information technologies and automated dispensing systems are widely used in health systems and are integral to many regulatory and external quality reporting systems, little data exist regarding their appropriate use or impact on patient safety.³² This is surprising given the cost and impact of technology on institutional infrastructure and practice. Nevertheless, there is consensus on the potential of technology to improve safety¹ and greater use in health systems is ensured.

Automation has the potential to reduce medication errors, but technology by itself will rarely prevent medication errors. Rather, it must be effectively integrated into the existing medication-use system and appropriately managed. In fact, if implemented and used unwisely, technology can make things worse. Dedicated professionals are needed to manage and oversee implementation, training, quality assurance, and ongoing support and maintenance.

Health-system leaders can be unrealistic in what they expect from automation. Automation can instill a false sense of security and carelessness in leaders and health-care professionals. For instance, it can cause professionals to neglect sound practices such as double- and triple-checking medication orders on the premise that, “The technology takes care of that.” Pharmacists need to advocate for adequate processes, training of personnel, staffing, and quality control checks. The following specific features would be desirable for reducing errors:

- Bar coding of medications should be maximized throughout the medication-use process, especially the dispensing and administration phases.
- Information technologies need to be integrated to provide the necessary information about the total care of patients.
- Pharmacists should have oversight of the dispensing process for automated dispensing systems.
- Pharmacists must have input into CDS protocols regarding medication use.
- Automation needs to free pharmacists for clinical activities that enhance the safety of patients.
- Regardless of whether or not state regulations exist to ensure safe use of technology, every healthcare organization needs to develop, enforce, and continuously improve multidisciplinary policies and procedures associated with patient safety.

Table 11-5 lists additional features of the use of automation in the medication-use process.

Regulatory Issues

In response to a lack of national standards and regulations for the safe use of automated dispensing systems, the National Association of Boards of Pharmacy (NABP) approved a document entitled *Model State Pharmacy Act and Model Rules* in May of 1997. The language in this act allows the definition of *dispensing* to include the use of automated technology, providing pharmacists with flexibility in the use of automation. But appropriately, it also required that such devices be used only in settings where an established program of pharmaceutical care ensures that a pharmacist reviews medication orders in accordance with good pharmacy practice. The act requires policies and systems to ensure safe and secure use of such devices but provides little guidance as to how. This act is intended to serve as a template for individual states to write (or rewrite) their State Pharmacy Practice Acts.

Despite the model act, some State Boards of Pharmacy erect barriers to automation. Some states require pharmacists to check every dose stocked in an automated dispensing device rather than allowing a system that incorporates technicians into the medication

KEY POINT...

Automation can instill a false sense of security and carelessness in leaders and healthcare professionals.

...SO WHAT?

Technology sometimes seems almost magical. It can do so many good things that we often forget machines are built and used by flawed human beings.

TABLE 11-5.

Desired Safety Features for Incorporating Automation into the Medication-Use Process

- A system must accommodate bar-coded unit dose medications and utilize the bar code capability for drug restocking, retrieval, and administering medications.
- A system should force the user to specify a reason whenever medications are accessed or administered outside of the scheduled administration time or dosage range; all such events are signaled visibly or audibly to the user and are electronically documented and reported daily for follow up.
- A unique bar code or user identification code and password are assigned to each user; audit trails of user actions must be reported in an easily viewed format and should include identification of the user, the medication, the patient for whom the drug was dispensed, and the time of the transaction.
- BCMA systems must be able to identify and document the patient, the medication, and the person administering using the scanning technology function.
- Devices are interfaced with the EHR, only allowing the nurse to view and access those medications that are ordered for a specific patient.
- Devices need electronic reminders to nurses when a medication dose is due (and by a different mechanism when it is past due).
- Hospital admit/discharge/transfer and medication order entry computer systems are interfaced with automation devices to provide caregivers with warnings about allergies, interactions, duplications, and inappropriate doses at the point of dispensing and/or administration.
- Patient-specific information used in the daily care of patients must be timely, accurate, and easily accessible.
- Pertinent patient- and medication-specific information and instructions entered into EHR are available electronically at the point of care (administration), and the system prompts the nurse to record pertinent information before administration may be documented.
- Real-time integration or interfaces exist for all steps in the medication-use process, starting at the point of prescribing, to order entry and dispensing, and through documentation of medication administration.

stocking process. Other states bog down automation initiatives with bureaucratic paperwork. Pharmacists need to play an active role in ensuring that their state's Pharmacy Practice Act enables automated dispensing systems and the transfer of electronic medication (prescription) orders.

Quality Assurance

Regardless of whether or not state regulations exist to ensure safe use of automated dispensing systems, it is extremely important that every organization develop, enforce, and continuously improve policies and procedures to ensure patient safety, accuracy, security, and confidentiality. Specific areas that should be addressed in an organization's policies for safe use of automated dispensing systems and technology include accurate inventory and stocking controls, dispensing procedures, security and breach of security patient confidentiality reporting, documentation, training of personnel, initial and ongoing competency assessment, routine quality assurance and safety checks, scheduled (and unscheduled) hardware and software maintenance and support, and contingency plans for maintaining safe systems and service in the event of unscheduled downtime.

ASHP Positions, Statements, and Guidelines

The need for guidance in pharmacy practice has increased greatly with the changes in health-care and with the influences from regulatory, accrediting, risk-management, financing, and

other bodies. The American Society of Health-System Pharmacists (ASHP) develops policies as positions, statements, and guidelines for pharmacy practice in integrated health systems (see www.ASHP.org/bestpractices). The policies of ASHP represent a consensus of professional judgment, expert opinion, and documented evidence to provide guidance and direction to pharmacy practitioners and other audiences who affect pharmacy practice. Their content should be assessed and adapted to meet the specific organization's needs. They are very useful in crafting departmental policies and in gaining pharmacist resources for coordination of automation projects within the organization. Policies contain varying levels of detail where positions are short pronouncements on one aspect of pharmacy practice; statements express a basic philosophy; and guidelines offer programmatic advice.

Current ASHP policy positions for automation and technology include the pharmacist's role in healthcare information systems (1211), clinical decision support systems (1212), the pharmacist's role in safe technology implementation, (1020), electronic health and business technology and services (0712), electronic information systems (0507), interoperability of patient-care technologies (1302), regulation of automated drug distribution systems (9813), and computerized prescriber order entry (0105) (see www.ASHP.org/bestpractices). ASHP also provides detailed statements and guidelines on the pharmacist's role in informatics; the pharmacy technician's role in informatics; bar code-enabled medication administration; and bar-code verification during inventory, preparations, and dispensing of medications, and for the safe use of automated dispensing devices.

The bar code-enabled medication administration statement, for example, advocates an industry standard for the placement of bar codes and information contained in a machine-readable bar code for unit dose, unit of use, and injectable drug products. This particular statement was very influential in the U.S. Food and Drug Administration's final rule requiring the use of a linear bar code to encode the national data code (NDC) number on most prescription drug products by April 2006. It is also ASHP's position that all medications be identified through machine-readable bar coding, as the use of bar-code technology at the point of medication administration will help to ensure safe, accurate, and documented medication administration. ASHP also advocates pharmacist involvement when key decisions are made in the planning, selection, implementation, and maintenance of electronic patient information systems. Specific ASHP policy positions, statements, and guidelines germane to this chapter can be found at www.ASHP.org/bestpractices.

SELECTING AUTOMATION WITHIN A HEALTH SYSTEM

Historically, automation had to result in proven cost reduction, quality improvement, improved service, and/or increased efficiency to be funded. While expense continues to be a major barrier, various regulatory entities, external quality reporting groups, and the news media have pressured many institutions to prematurely invest heavily in new technologies based on a theoretic but unproven safety benefit.

Integrated health systems should not view automation and technology as a means to an end, but rather as a series of sophisticated tools to help them optimize the medication-use process. The value achieved by implementing new technology within organizations depends primarily on three factors: the efficiency of the system being replaced, the level of detail applied to managing and making the most of the system following implementation, and cooperation between departments to ensure success of the system. In 2008, The Joint Commission released a sentinel event alert (i.e., report of an unexpected occurrence involving death or serious injury), which started a focus on the safe implementation of health information and converging technologies. In 2009, the Health Information Technology for Economic and Clinical Health (HITECH) Act was signed into law and established

programs to improve health care quality, safety, and efficiency through the promotion of health IT, including electronic health records and private and secure electronic health information exchange. This was followed in 2012 by the Food and Drug Administration Safety and Innovation Act (FDASIA), which called for a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework for health IT (e.g., medical mobile applications) that promotes innovation, protects patient safety, and avoids regulatory duplication. The enactment of these new laws heighten the focus on health information technology and the creation of new resources or tool kits to ensure its implementation and use does not negatively impact the safety of patients. Suggested actions to help institutions prevent harm to patients include:

- Examine workflow processes and procedures for risk and inefficiency and fixing issues prior to implementing technology.
- Actively involve frontline clinicians, staff, and IT staff during the planning, selection, design, reassessment, and ongoing quality improvement.
- Include a pharmacist in the planning and implementation of any technology involving medications; during implementation, provide continual monitoring to identify problems and promptly address them.
- Establish a well-defined training program for all staff who will be using the technology.
- Design a system that mitigates potentially harmful medication orders by developing standardized order sets and guidelines on paper, approve them through the pharmacy and therapeutics committee (P&T), and test them before going live.
- After implementation, continually reassess and enhance the safety and effectiveness of the technology.³³

Within most hospitals, there is consensus that the inpatient medication-use process should be automated as much as possible but questions and debate remain as to how to do so. There really is no single approach to automation, and any approach can succeed or fail depending on how well it is managed.^{34,35} **Table 11-6** provides questions to consider in choosing automation vendors including considerations of desired automation system functionality, hardware and software technical requirements, installation and training support, and vendor/system reliability.

COST JUSTIFICATION OF AUTOMATED SYSTEMS

Historically, pharmacists could justify the costs of new automation if the technology improved the capture of medication charges or freed pharmacists to perform new billable services. This is no longer the case due to changes in hospital reimbursement from government and private payers. Now, detailed return-on-investment (ROI) analyses are often needed to demonstrate that the technology makes good financial sense for the organization. The goal of ROI analysis is to compare an organization's total costs before and after the implementation of automation and to demonstrate a positive ROI if a decision is made to support the automation. Chapter 13, Basics of Financial Management and Cost Control, provides details on what goes into conducting ROI analyses.

AUTOMATION'S IMPACT ON PHARMACY MANPOWER

Some pharmacists have been concerned over the years that increased use of automation, coupled with expansion of the use of pharmacy technicians and prescription mail order services, would reduce the demand for pharmacists. Fortunately, that has not been the case because efficiencies in automation have been offset by increased demand for pharmacy personnel due to an aging U.S. population, organizational recognition of the value of

clinical pharmacists, and the soaring number and complexity of medications used in hospitals. Still, the demand for dispensing pharmacists in comparison to clinical pharmacists will likely decrease as automated dispensing and patient monitoring technologies advance.

Automation will permit technicians to take over much of medication dispensing and distribution. Technicians will increasingly be expected to oversee automated dispensing systems and possibly smart IV pump and BCMA systems. This will permit pharmacists to move from distributive to clinical roles.

As technology provides pharmacists with opportunities to be more involved with direct care of patients, pharmacists will need to advocate for and promote the value of pharmacist patient care services to physicians and administrators. If not, some health-system pharmacist positions may be displaced by technology. Indeed, automation is currently forcing the issue of pharmacists' professional role in the redevelopment of health systems.

Given that continued automation of the dispensing process is inevitable, future work activities of pharmacists depend primarily on four things: (1) the breadth of tasks a pharmacy technician is legally allowed to perform (and/or allowed to perform by an employer); (2) the extent to which pharmacists are reimbursed for medication therapy management services; (3) the level of productivity that can be achieved through automated systems; and (4) the extent to which pharmacists are able to demonstrate improved quality and overall lower cost of patient care as a result of their role on the patient care team. Current dispensing automation clearly creates the potential for pharmacists to focus more of their time on direct patient care activities instead of product preparation.

KEY POINT . . .

Automation is currently forcing the issue of pharmacists' professional role in the redevelopment of health systems.

. . . SO WHAT?

Automation frees pharmacists from routine and repetitive tasks. It allows pharmacists to seek new opportunities to improve patient medication care. Indeed, if pharmacists do not identify professional roles in health systems, they risk becoming obsolete.

Future Roles of Pharmacy Personnel as a Result of Automation

The transformation of the pharmacist role from distributor of drugs to cognitive provider of care has largely resulted from pharmacists' access to patient-specific information about diagnosis, laboratory results, treatment progress, and the patient's entire drug therapy regimen. Integrated delivery systems and automation will continue to provide pharmacists with opportunities to work more closely with physicians and patients to ensure appropriate drug therapy decisions and outcomes. Toward this end, pharmacists must continue to assume increased accountability for understanding patient drug-related needs; identifying, solving, and preventing drug-related problems; designing and initiating drug therapy plans; and continuing drug therapy plans once they are initiated. Pharmacists also have a responsibility to create systems to improve the quality and safety of drug distribution and administration. Pharmacists must possess good time management and problem-solving skills and be able to focus the majority of their time on issues related to high-risk drugs and high-cost diseases, while paying particular attention to the dosing of high-cost drugs for all patients.

Pharmacists may find themselves working more in a virtual world of electronic information management where they never even touch a drug or paper prescription. Clinical pharmacists in the virtual world may have three primary responsibilities: to assess patient

TABLE 11-6.

Automation Selection Criteria

- Can the vendor provide you with established policies and procedures for integrating the system into the pharmacy’s daily work flow, clearly defining pharmacist and technician responsibilities and clearly defining system downtime procedures?
- Cost-benefit analysis: Will reduced supply and labor expenses offset the cost of the automation? What is the potential increased revenue as a result of the automation?
- Does the system produce useful statistical and managerial reports, and do they provide a report writing and analysis tool?
- How does the system utilize bar-code technology to improve accuracy of transactions?
- How long has the company been in business, and how many units do they have in operation?
- How much space will the automation require, and is remodeling required?
- How much time is required for routine maintenance and equipment servicing? Does the company provide full service as well as routine and emergency software and hardware maintenance? What is the cost of this maintenance, and how is it provided? Will routine maintenance disrupt workflow?
- How secure is the system?
- Is training interactive and computer-based? How will new users be trained on the system?
- Is the automation compatible with the organization’s strategic goals?
- Is the company willing to guarantee a maximum percent downtime?
- Is the system compatible with existing information systems? Has the company interfaced their system with your EHR in another organization? If not, what is the cost for building this interface? Who maintains the interface?
- What do existing customers say about the accuracy and reliability of the system, ease of use, and unscheduled downtime?
- What impact will the automation have on other departments? How are those departments involved in the selection process?
- What impact will the automation have on patient safety?
- What impact will the system have on controlled substance accountability and overall inventory control?
- What sets this company’s product apart from their major competitors?
- Will the automation enable the provision of new clinical services?
- Will the vendor adapt the technology to meet your needs, goals, and objectives rather than expect your system to be redesigned to fit their product?
- Will the vendor provide you with a list of all current users?
- Will the vendor’s training and implementation support meet your expectations and needs?

compliance and medication-related outcomes, drug and disease education, and intervention. The optimization of such roles in both inpatient and ambulatory environments offers opportunities to avoid displacement of pharmacists by automation.



SUMMARY

Automation is not a panacea for the problems in pharmacy practice. There is no perfect technology, and automated systems must be well managed to provide cost-effective services and support the profession’s transition to pharmacist patient care services. To be successful in the future, pharmacists must view automation-induced productivity and efficiency

as desired goals, not as threats to their work. Optimized use of automation to perform distributive functions currently performed by pharmacists and technicians is essential in providing pharmacists with additional time to take care of patients. Every change must be implemented with an understanding of **human factors engineering** and safety science, as even good changes will create unexpected new hazards. In addition, policies and procedures must change as the use of technology increases to ensure a safe and proper medication-use infrastructure.

Pharmacy automation will continue to progress. Efficient EHRs, fully automated dispensing systems, and virtual patient monitoring systems will be commonplace in the medication-use process of the future. Pharmacists have a choice to make such systems successful or to resist change. Opportunities exist for pharmacists who embrace automation, provide leadership to ensure safe and efficient automation systems, and innovate through automation.

SUGGESTED READING

ASHP Guidelines on Safe Use of Automated Compounding Devices for the Preparation of Parenteral Nutrition Admixtures. Available at: <http://www.ashp.org/menu/PracticePolicy/PolicyPositionsGuidelinesBestPractices/BrowsebyTopic/Automation.aspx>.

ASHP Guidelines on Safe Use of Automated Dispensing Devices. Available at: <http://www.ashp.org/menu/PracticePolicy/PolicyPositionsGuidelinesBestPractices/BrowsebyTopic/Automation.aspx>.

ASHP Policy Position on Automation and Information Technology. Available at: <http://www.ashp.org/menu/PracticePolicy/PolicyPositionsGuidelinesBestPractices/BrowsebyTopic/Automation.aspx>

ASHP Statement on Bar-Code-Enabled Medication Administration Technology. Available at: <http://www.ashp.org/menu/PracticePolicy/PolicyPositionsGuidelinesBestPractices/BrowsebyTopic/Automation.aspx>.

ASHP Statement on Bar-Code Verifications during Inventory, Preparation, and Dispensing of Medications. Available at: <http://www.ashp.org/menu/PracticePolicy/PolicyPositionsGuidelinesBestPractices/BrowsebyTopic/Automation.aspx>.

ASHP Statement on the Pharmacist's Role in Clinical Informatics. Available at: <http://www.ashp.org/menu/PracticePolicy/PolicyPositionsGuidelinesBestPractices/BrowsebyTopic/Automation.aspx>

ASHP Statement on Pharmacist's Role with Respect to Drug Delivery Systems and Administration Devices. Available at: <http://www.ashp.org/menu/PracticePolicy/PolicyPositionsGuidelinesBestPractices/BrowsebyTopic/Automation.aspx>.

ASHP Statement on Pharmacy Technician's Role in Pharmacy Informatics. Available at: <http://www.ashp.org/menu/PracticePolicy/PolicyPositionsGuidelinesBestPractices/BrowsebyTopic/Automation.aspx>.

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CHAPTER REVIEW QUESTIONS

1. **Automation is one solution pharmacy departments have used to reduce the amount of pharmacist and technician labor required to perform dispensing activities.**

- a. True
- b. False

Answer: a. True. As the profession has accepted increased responsibility for improving patient outcomes through implementation of pharmacist patient care services, automation has been relied on to free the pharmacist from technical tasks.

2. **Medication errors resulting in adverse drug events (ADEs) have effects only on the patients who suffer from a medication error.**

- a. True
- b. False

Answer: b. False. Medication errors resulting in ADEs (preventable ADEs) can cause significant patient harm and consumption of resources in the form of increased lengths of stay, increased cost of care, rework time, malpractice claims, and patient costs (suffering and lost productivity).

3. **When smart pumps are integrated with an EHR platform, nursing staff will no longer need to _____ (select all that apply).**

- a. Manually program pumps
- b. Hang medications on an IV pole
- c. Manually select medications from the pump library
- d. Insert IV lines for medication administration

Answers: a and c. As smart pumps are integrated with an EHR platform, medical record will automatically select medications and program the pump's infusion parameters based on the provider's order.

4. **Inefficient processes for product procurement and inventory management can hamper a pharmacy's ability to provide direct patient care.**

- a. True
- b. False

Answer: a. True. Poor product procurement systems can result in pharmacists spending excessive time trying to locate products.

5. **The goal of return on investment (ROI) analysis is to compare an organization's total costs before and after the implementation of automation.**

Answer: True. Detailed ROI analyses are often needed to demonstrate that the technology makes good financial sense for the organization.

6. **Carousel dispensing technology (CDT) provides the maximum efficiency and safety when dispensing medications.**

- a. True
- b. False

Answer: b. False. Although CDT will result in improved dispensing accuracy and labor efficiency, no single technology configuration has been shown to be best.

7. Automation will permit technicians to take over much of medication dispensing and distribution.

- a. True
- b. False

Answer: a. True. Technicians will increasingly be expected to oversee automated dispensing systems and possibly smart IV pump and BCMA systems. This will permit pharmacists to move from distributive to clinical roles.

8. _____ technology offers the potential to dramatically reduce the risk of medication errors during the administration phase of the medication-use process.

Answer: Bar-coded medication administration (BCMA). BCMA can reduce medication administration errors that occur as the following discrepancies: wrong patient, wrong drug, wrong dose, or wrong time. Other benefits include improved patient safety, documentation accuracy, and nurse satisfaction as well as public and patient relations that can result from a well-designed and implemented BCMA system. These benefits dramatically outweigh BCMA implementation challenges.

9. Food and Drug Administration Safety and Innovation Act of 2012, FDASIA, called for strategy and recommendations on an appropriate, risk-based regulatory framework for health IT (e.g., medical mobile applications).

- a. True
- b. False

Answer: a. True. The FDASIA called for a strategy and recommendations on an appropriate regulatory framework for health IT, including mobile application to promote innovation and promote patient safety

10. Selection of automation should include an analysis of:

- a. Desired automation system functionality
- b. Hardware and software technical requirements
- c. Installation and training support
- d. Background checks for vendor systems
- e. All of the above

Answer: e. All of the above. Automation selection should include a complete analysis of desired automation system functionality, hardware and software technical requirements, installation and training support, and vendor/system background reference checks.

CHAPTER DISCUSSION QUESTIONS

1. Describe your ideal automation selection team in terms of the personnel needed and purpose for each member's inclusion.
2. Compare the advantages and disadvantages of using an eMAR with bar-code reading devices for documenting medication administration.
3. Describe the desired features for incorporating automation into the medication-use process.
4. Describe the effect automation can have on the future of health-system pharmacy practice. How will the role of the pharmacist change as a result of advances in automation?
5. Given a choice of automation products to implement, which solution would you choose to implement first and why?

CHAPTER 12

Purchasing and Inventory Control

Jerrod Milton

LEARNING OBJECTIVES

After completing this chapter, readers should be able to:

1. Describe the steps in purchasing medications and inventory control.
2. Define key terminology in purchasing and inventory control.
3. Discuss the processes for managing medication inventory.
4. Identify products that require special handling.

KEY TERMS AND DEFINITIONS

- **Economic order quantity (EOQ):** A model of inventory control (also known as the minimum cost quantity approach) that uses past history of inventory use, costs, and demand to develop an accounting model that predicts optimal inventory order quantities to minimize order costs and inventory holding costs.
- **Group purchasing organizations (GPOs):** Purchasing groups consisting of health systems and hospitals that join together to obtain greater collective buying power.
- **Inventory carrying costs:** All costs associated with inventory investment and storage; sometimes called holding costs. It might include interest, insurance, taxes, and storage expenses.
- **Inventory turns:** The fraction of a year that an average item remains in inventory. High inventory turnover is a sign of efficiency because inventory is constantly at work and generating revenue. Low turnover is a sign of inefficiency.
- **Just-in-time inventory management:** A philosophy of inventory management where products are ordered and delivered at just the right time—when they are needed for patient care—with a goal of minimizing wasted steps, labor, and cost. The goal is to neither overstock nor understock products.
- **Order book:** A list of products that need to be ordered from a supplier.
- **Pareto/ABC analysis:** Based on the principle stating that a relatively small number of drugs account for a disproportionate amount of drug usage in a health system. Thus, a Pareto ABC analysis groups inventory products by aggregate value and volume of use into three groupings (A, B, and C). Products in group A are the small percentage of items that make up the greatest amount of inventory cost. Groups B and C make up decreasingly less cost.
- **Par-level systems:** Based on the principle that individual inventory drug use falls within a predictable range or “par-level.” In these systems, a range is identified and minimum and maximum order quantities are set. Inventory is ordered in a way that maintains amounts within the par-level.
- **Perpetual inventory:** A record of inventory that is constantly updated when items are added or subtracted from inventory.

- **Pharmacist in charge:** Typically an individual who has accepted the responsibility for the complete supervision, management, and compliance with all federal and state pharmacy laws, rules, and regulations governing the practice of pharmacy within the prescription department.¹
- **Prime vendor agreement (PVA):** A contract between a health-system pharmacy and a licensed wholesale distributor wherein the pharmacy agrees to purchase most of its pharmaceuticals from a single distributor in return for advantageous pricing, terms of drug delivery, and support services (e.g., providing the pharmacy with electronic order entry/receiving devices and bar-coded shelf stickers).
- **Resource Conservation & Recovery Act (RCRA):** The public law enforced by the EPA that creates the framework for the proper management of hazardous and non-hazardous solid waste.^{2,3}
- **Stock rotation:** The process of placing products nearest to the time of expiration at the front of the shelf or storage unit so that they will be used first.



INTRODUCTION

In 2001, the Institute of Medicine (IOM) in Washington, DC, released *Crossing the Quality Chasm: A New Health System for the 21st Century*, which provides a detailed examination of the tremendous divide between what we know to be good healthcare and the care that Americans actually receive. Although a systematic transformation has begun, the challenge to close the chasm remains largely on healthcare leaders and clinicians. The quality of healthcare must be improved, and the profession of pharmacy is not exempt from this ideal. The IOM defines quality across six important dimensions that include safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity.⁴

Effective pharmacy purchasing and inventory control measures are essential to fulfilling this ideal. As fundamental elements of the medication-use system, they support these aims of quality in healthcare. The dimensions of quality included in this context are the following:

- Safety (to cause no harm)
- Efficiency (reduce waste/excessive cost)
- Effectiveness (every patient who would benefit from a particular drug should receive it)
- Timeliness (appropriate time to heal)

Purchasing and inventory control processes impact the ability of the system to provide the right drug, to the right patient, in the right amount, in the right dosage form, by the right route of administration, and at the right time and frequency. Therefore, an effective purchasing and inventory control system requires the understanding and active participation of all pharmacy staff.

This chapter describes the basic principles of pharmaceutical purchasing and inventory control. It applies to all types of pharmacy settings including decentralized, centralized, home infusion, and ambulatory care pharmacy operations.

FORMULARY SYSTEM

The formulary is the cornerstone of the purchasing and inventory control system.⁵⁻⁷ The pharmacy and therapeutics (P&T) committee develops and maintains the formulary. This group generally comprises medical and allied health staff such as physicians, pharmacists, nurses,

and administrators, although other disciplines may be present (e.g., dietitians, medication safety officers, risk managers, case managers). These professionals collaborate to ensure that the safest, most effective, and economical medications are included on the formulary.

The products on the hospital formulary dictate what the hospital pharmacy should purchase and keep in inventory. Third-party prescription drug benefit providers will also establish plan-specific formularies for their ambulatory patients. Ambulatory (retail) pharmacy staff frequently encounter insurance plan-specific drug formularies in serving their patients and adjust their inventory accordingly. Most retail pharmacies do not rigidly restrict items in their inventory because, in this setting, inventories are largely dependent on the dynamic needs of their patient population and their patients' respective insurance plans. Therefore, the concept of formulary management differs greatly depending on the practice setting (e.g., that of the hospital compared with that of the retail pharmacy).

The hospital formulary is generally available in print or online formats. The formulary is produced exclusively for all health practitioners involved in prescribing, dispensing, and monitoring medications; this tool is formatted generally to inform users of product availability, the appropriate therapeutic uses, and recommended dosing of medications. Some formulary systems include comprehensive drug monographs, which serve as a primary drug information resource to practitioners within the system of care. Most formularies are organized alphabetically by the generic drug's name, which is typically cross-referenced with the trade name products. In most cases, the drug storage areas in the pharmacy are arranged alphabetically by either the generic or trade name of the drug. Therefore, the formulary can help the pharmacy personnel determine if a product is stocked in the pharmacy and where it would be shelved.

Drugs are added and deleted from the formulary on a regular basis with the frequency varying among organizations. Formulary publications should remain current (ideally, with information being updated in real-time). Loose-leaf formularies and those maintained online can be updated continuously in a timelier manner, whereas bound formulary handbooks rely on supplementary updates or publication of serial editions.

Important information available in the formulary includes the dosage form, strength, concentration, package size(s), common side effects, and administration instructions. Some institutions also indicate the actual or relative cost of a given item to guide the prescribing of the most cost-effective alternatives. When selecting a drug product from inventory, the technician must consider all product characteristics such as name, dosage form, strength, concentration, and package size. In practice settings where an electronic health record (EHR) system is employed, it is possible to have real-time access to online formulary publications at the point where and when the provider places a medication order. Detailed review and consideration of each listing helps minimize errors in product selection.

MANAGING THE PURCHASING AND INVENTORY CONTROL SYSTEM

Some pharmacies employ a few specialized individuals charged with managing the purchasing and inventory process of pharmaceuticals, while others utilize numerous individuals in the role.⁸ Limiting the number of individuals to a specialized few permits greater expertise and efficiency, but it can also keep the remaining pharmacy staff uninformed and unengaged in purchasing and inventory control. This can be a problem if there is turnover among the specialists. It can also lead to a lack of appreciation of the importance of purchasing and inventory control by those who are uninformed and unengaged. Cross-training individuals in purchasing and inventory control can help them fully understand the system and make better decisions in daily practice to support patient care.

State-of-the-art practice in purchasing and inventory control uses sophisticated computer software algorithm technologies to manage purchasing and receiving of pharmaceuticals from a drug supplier.⁹ Other practices utilize technology, including product bar codes and hand-held computer devices that facilitate electronic data transmission in this process for procurement and purchase order generation and for electronic receiving processes. Using computer technology for these purposes has many obvious benefits including up-to-the-minute product availability information, comprehensive reporting capabilities, accuracy, tighter inventory control, and efficiency. It also helps in complying with various pharmaceutical purchasing contracts by keeping track of terms and reminding about deadlines and contract pricing deals.

RECEIVING AND STORING PHARMACEUTICALS

Receiving medications from suppliers is one of the most important parts of the pharmacy operation. A poorly organized and executed receiving system can put patients at risk and elevate healthcare costs. For example, if the pharmacy received the wrong concentration of a product or an outdated product, it could lead to a dosing error or a delay in therapy, which is certainly counter to our quality aims. Misplaced products or out-of-stock products also jeopardize patient care as well as the efficiency of the department; both are undesirable and costly outcomes.

Receiving Process

Some pharmacies follow a policy that dictates the person who receives pharmaceuticals cannot be the person who orders them. This process is especially important for controlled substances because it effectively establishes a check in the system to minimize potential drug-diversion opportunities.

In a reliable and efficient receiving system, the receiving personnel verify that the shipment is complete and intact (i.e., they check for missing or damaged items) before putting items into circulation or inventory.⁶ The receiving process begins with the verification of the boxes containing pharmaceuticals delivered by the shipper. The person receiving the shipment first verifies that the name and address on the boxes are correct and that the number of boxes matches the shipping manifest. Many drug wholesalers use rigid plastic crates to deliver orders because they protect the contents of each shipment better than foam or cardboard boxes. These crates are also environmentally friendly because they are returned to the wholesaler for cleaning and reuse. Regardless, each box should be inspected for gross damage.

Products with a cold storage requirement (i.e., refrigeration or freezing) should be processed first. The shipper is responsible for taking measures to ensure the cold storage environment is maintained during the shipment process and will generally package these items in a shippable foam cooler that includes frozen cold packs to keep products at the correct storage temperature during shipment.

KEY POINT . . .

Some pharmacies require that the person who receives pharmaceuticals cannot be the person who orders them.

. . . SO WHAT?

The potential for drug diversion to occur is substantial during the process of ordering and receiving. Appropriate controls (checks and balances) should be implemented and include diverse roles. If a single employee single-handedly controls these checks and balances, the greater the possibility is for that employee to divert products and to cover up that diversion.

Receiving personnel play a critical role in protecting the pharmacy from financial responsibility for products damaged in shipment, products not ordered, and products not received. Any obvious damage or other discrepancies with the shipment, such as a breach in the cold storage environment or delivery of an incorrect or outdated product, should be noted on the shipping manifest; if warranted, that part of the shipment should be refused. Ideally, identifying gross shipment damage or incorrect box-counts should be performed in the presence of the delivery person and should be well documented when signing for the order. Identifying other problems after delivery personnel have left the premises such as mistaken picks, product dating, or internally damaged goods, must be resolved according to the vendor's policies. Most vendors have specific procedures to follow in reporting and resolving these sorts of discrepancies.

The next step of the receiving process entails checking the newly delivered products against the receiving copy of the purchase order. This generally occurs after the delivery person has left. A purchase order, created when the order is placed, is a complete list of the items that were ordered. Traditionally, a purchase order will be executed in multiple copies including an original file copy, a copy used in the receiving process, and a copy for the supplier.

The person responsible for checking products into inventory uses the receiving copy. This ensures that the products ordered have been received. The name, brand, dosage form, size of the package, concentration strength, and quantity of product must match the purchase order. Once the accuracy of the shipment is confirmed, the purchase order copy is generally signed and dated by the person receiving the shipment. At this point, the expiration date of products should be checked to ensure that they meet the department's minimum expiration date requirement. Frequently, departments will require that products received have a minimum shelf life of 6 months remaining before they expire. Otherwise, the products may expire before use and have to be wasted (see Resource Conservation and Recovery Act [RCRA] implications below) or returned to the supplier. On occasion, the manufacturer/wholesaler may inadvertently ship an excess quantity of an ordered product to the pharmacy. The ethical response is to notify the manufacturer or wholesaler of this situation immediately and subsequently arrange for the return of any excess quantity.

Controlled substances require additional processing on receipt.^{6,10} Traditionally, regulations specific to Schedule II controlled substances require Drug Enforcement Administration (DEA) Form 222 to be completed on receipt of these products and filed separately with a copy of the invoice and packing slip accompanying each shipment. The DEA also allows for controlled substances to be procured without the supporting paper Form 222. Secure electronic technology known as the *Controlled Substances Ordering System (CSOS)* allows for order transmission of controlled substance orders without use of Form 222 as long as the purchaser enrolls with the DEA to acquire a digital CSOS certificate.¹¹ CSOS is associated with the following benefits: freedom of ordering as it includes Schedules I–V without the line item limit encountered on the paper Form 222; faster transactions facilitate just-in-time ordering and inventory management; ordering errors are reduced, promoting accuracy; and transaction costs are lower based on ordering efficiency, reduction in rework, and reduced paperwork associated with controlled substances.

If a pharmacist or pharmacy technician other than the receiving technician removes a product from a shipment before it has been properly received and cannot locate the receiving copy of the purchase order, then a written record of receipt should be created. This is done by listing the product, dosage form, concentration/strength, package size, and quantity on a blank piece of paper or on the supplier's packing slip/invoice and checking off the line item received. In both cases, the name of the person receiving the product should be included, and the document should be given to the receiving technician to avoid confusion and an unnecessary call to the wholesaler or manufacturer.

Storing Process

Once the product has been received properly, it must be stored properly.¹² Depending on the size and type of the pharmacy operation, the product may be placed in a bulk, central storage area or into the active dispensing areas of the pharmacy. Some operations are of sufficient scale and employ robotic technology to store, sort, dispense, and automate the inventory management process. Examples include the Swisslog, Omnicell's Pharmacy Carousel, and Aesynt's Insyte Medication Logistics (**Figure 12-1**). These technologies are intended to optimize medication inventory, reduce waste, enhance productivity, and liberate pharmacy resources so they can more readily contribute in the course of clinical care.

In any case, prior to placement of received items into stock, the expiration date of the product should be compared with those products currently in stock. Products already in stock that have expired should be removed and appropriately segregated. Products that will expire in the near future should be highlighted and placed in the front of the shelf or bin. This is a common practice known as **stock rotation**. The newly acquired products will generally have longer shelf lives and should be placed behind packages that will expire before them. Stock rotation is an important inventory management principle that encourages the use of products before they expire and helps prevent the use of expired products and waste. It is safe to assume that the first-in, first-out (FIFO) method of inventory management is applied when it comes to pharmaceutical products.

All stock should be organized and stored at temperature and humidity levels recommended by manufacturers and defined by the United States Pharmacopoeia (USP). **Table 12-1** identifies the optimum storage temperatures and humidity conditions. Periodic checks

of refrigeration and other storage areas should be conducted to ensure they fall within recommended ranges.



FIGURE 12-1. Robotic pharmaceutical inventory management.

PRODUCT HANDLING CONSIDERATIONS

Role of the Pharmacy Technician

Generally, pharmacy technicians spend more time handling and preparing medications than do pharmacists. This presents pharmacy technicians with the critical responsibility of assessing and evaluating each product from both a content and a labeling standpoint. It also provides the technician with an opportunity to confirm that the receiving process was performed properly.

Just as checking the product label carefully upon prescription filling is important, taking the same care when receiving pharmaceuticals and accurately placing them in their storage location is essential. The pharmacy technician should read product pack-

TABLE 12-1.

Defined Storage Temperatures and Humidity¹³

Freezer	(-)-25° to (-)-10°C	(-)-13° to 14°F
Cold (refrigerated)	2° to 8°C	36° to 46°F
Cool	8° to 15°C	46° to 59°F
Room temperature	The temperature prevailing in a working area	
Controlled room temperature	20° to 25°C	68° to 77°F
Warm	30° to 40°C	86° to 104°F
Excessive heat	Any temperature above 40°C (104°F)	
Dry place	A place that does not exceed 40% average relative humidity at controlled room temperature or the equivalent water vapor pressure at other temperatures. Storage in a container validated to protect the article from moisture vapor, including storage in bulk, is considered a dry place.	

aging carefully, rather than rely on the general appearance of the product (e.g., packaging type, size or shape, color, logo) or its storage location because a product's appearance may change dynamically based on product availability, contractual changes, marketing interests of the manufacturer, or similarity of drug name and dose. Because of these dynamics, the containers of products may frequently appear to be similar to other products. Technicians play a vital role in minimizing dispensing errors that may occur because of human fallibility. They are generally the first in a series of checks involved in an accurate dispensing process.

When performing purchasing or inventory management roles, the technician must pay close attention to the product's expiration date. For liquids or injectable products, the color and clarity of the items should also be checked for consistency with the product standard. Products with visible particles, an unusual appearance, or a broken seal should be reported to the pharmacist. A good rule applicable to pharmacy practice is to *never proceed in the face of uncertainty*, but rather, stop and resolve the concern.

Because pharmacy technicians handle so many products each day, they are in a perfect position to identify packaging and storage issues that could lead to errors. The technician should pay close attention to these three main issues:

1. **Look-alike/sound-alike (LASA) products** — Stocking products of similar color, shape, and size could result in error if someone fails to read the label carefully. All staff members should be alerted to look-alike or sound-alike products (**Figure 12-2**).¹⁴
2. **Misleading labels** — Sometimes the company name or logo is emphasized on the label instead of the drug name, concentration, or strength (**Figure 12-3**).^{14,15}
3. **Product storage** — Storing products that are similar in appearance adjacent to one another can result in error if someone fails to read the label (**Figure 12-4**).^{15,16} Adequate, uncrowded space should be allocated to proper medication storage. Appropriate product grouping and separation should also occur in the organization of the inventory. In other words, pharmaceutical dosage forms should not be randomly intermingled in the storage area but rather thoughtfully organized.

Alerting other staff members to products that fall into one of these categories is essential. Some pharmacies routinely discuss product-handling considerations at staff meetings or in departmental newsletters. Errors may be averted by simply relocating a LASA product

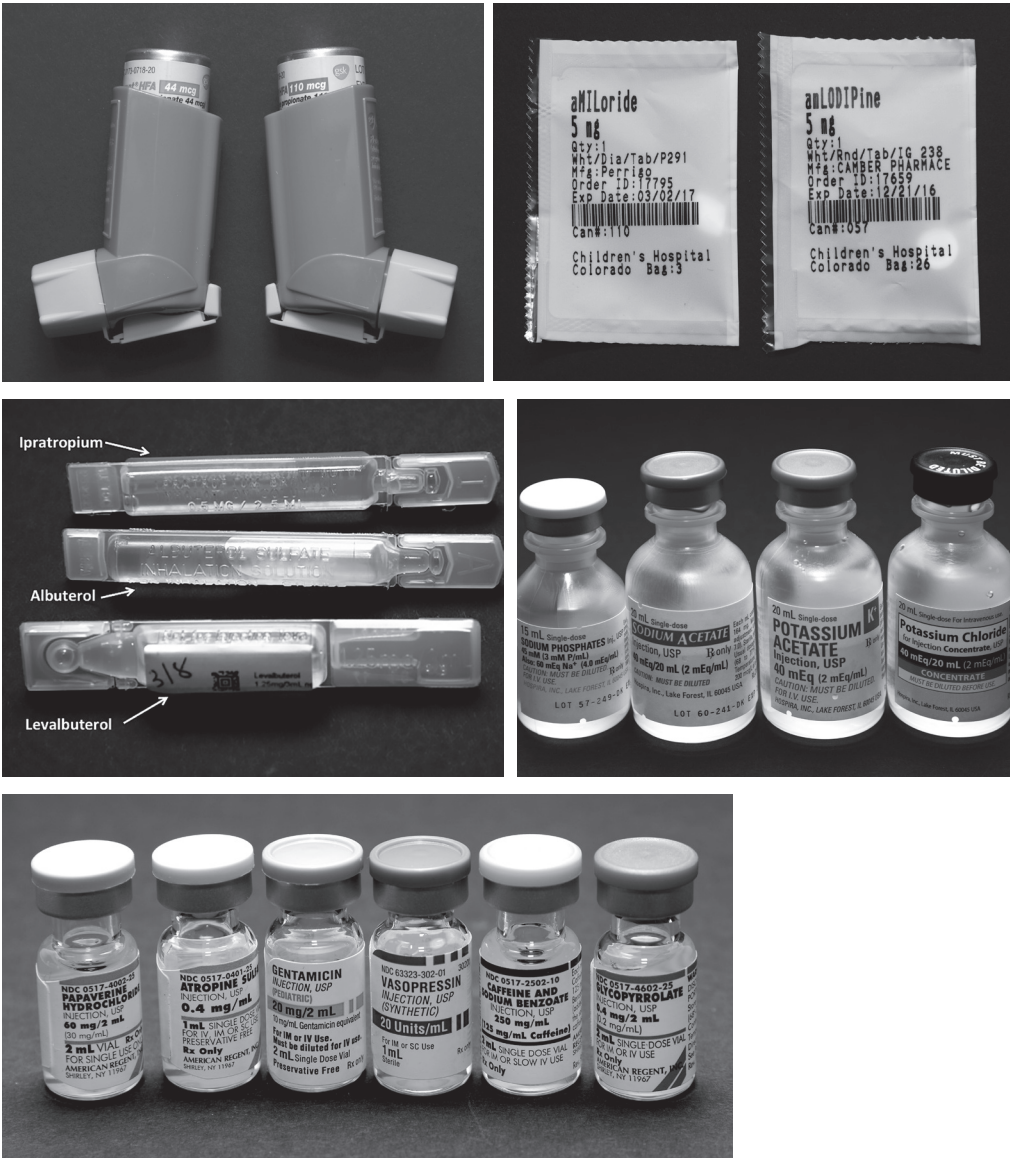


FIGURE 12-2. Look-alike/sound-alike products.



FIGURE 12-3. Product labeling; emphasis on manufacturer name.

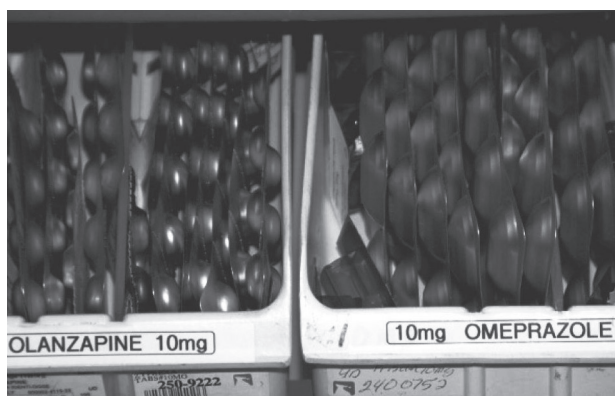


FIGURE 12-4. Product inventory; shelf position.

or by placing warning notes (i.e., auxiliary labeling or highlights) on the shelf or directly on the product itself. Pharmacy technicians should also discuss their concerns with coworkers and advocate changes to products with poor labeling.

Resource Conservation and Recovery Act (RCRA) Regulations

The U.S. Environmental Protection Agency (EPA) and in many cases, the state's hazardous waste regulatory agency enforces hazardous waste laws. In the context of handling and disposal, numerous pharmaceutical products are considered to be hazardous wastes. Examples of hazardous drug products commonly encountered in the institutional and ambulatory pharmacy practice environment include warfarin, epinephrine, nicotine, mineral preparations, and antineoplastic agents. (*Note:* The list of these medications is extensive and dynamic.) The practical considerations necessary to be compliant with state and federal waste regulations exceed the scope of this chapter. However, a cursory knowledge that these laws exist and through practical considerations (e.g., inventory procurement, receiving, dispensing, waste-stream management processes) is important. Full compliance with these regulations is essential to avoid state and federal sanctions.^{2,3}

KEY POINT . . .

Pharmacy technicians have key responsibilities in assessing the labeling and ensuring the quality of each product received and placed into inventory.

. . . SO WHAT?

Some pharmacists may have difficulty delegating responsibilities to well-trained, competent pharmacy technicians.

These technicians are occasionally micromanaged and discouraged from acting as independent contributors in healthcare delivery. In many cases, competent technicians are as good, if not better than pharmacists at the technical aspects of medication purchasing and distribution. Empowering technicians to take on tasks such as ensuring the quality of the inventory is essential for a well-run medication distribution system.

MAINTAINING AND MANAGING INVENTORY

An inventory management system is an organized approach designed to maintain just the right amount of pharmaceutical products in the pharmacy at all times. A key goal of inventory management is to maximize **inventory turns**, meaning simply that products should be

used and not remain on the shelf aging. Although drugs left on the shelf could be considered financial assets, their useful shelf life wanes with each passing day and excessive inventory is an unproductive asset, tying up money and resources that can be used in running other elements of the pharmacy operation or business as a whole. *Inventory turns*, defined in accounting terms, are the fraction of a year that an average item remains in inventory.

A simple means of calculating inventory turns in a given period is to divide the total purchases in that period by the value of physical inventory taken at one point in time. For example, if total pharmaceutical purchases for fiscal year (FY) 2015 were \$10,243,590, and the physical inventory value on 12/31/2015 was \$521,550, then the calculated inventory turns for FY2015 would be 19.6 times ($\$10,243,590 / \$521,550 = 19.6$). This method assumes a relatively constant volume of pharmaceutical purchases and constant residual inventory over time. If greater variability in purchasing volume exists, then the average of 2-year purchasing statistics could be used as the numerator in the formulas represented. Like any business, performing a physical inventory at approximately the same time in every fiscal period will produce more meaningful, comparable results. Seasonal variables and new drugs entering the formulary should be considered in comparative analyses.

Inventory turnover is a way of measuring the productivity of a pharmacy's inventory use and the use of invested capital. High inventory turnover is a sign of quality (i.e., efficiency) because inventory is constantly at work and generating revenue, which translates to value. Low inventory turnover is a sign that product (capital) is sitting unused on the shelf and is a signal of a lesser quality operation (i.e., inefficiency). Financial liquidity is a favorable term largely established by the amount of cash a business has in bank accounts. Liabilities such as payroll expenses, notes due to suppliers, taxes, and interest payments depend on a firm's financial liquidity. Turning cash into inventory goods (i.e., pharmaceutical inventory) when the consumer demands of the business do not require the inventory diminishes liquidity.

A variety of inventory management systems are used in pharmacy practice, ranging from simple to complex. They include the order book, the minimum/maximum (par) level, the Pareto (ABC) analysis, the economic order quantity (EOQ), and just-in-time systems.⁷ Each of these systems attempt to maximize inventory turnover while at the same time minimize inventory carrying costs (or holding costs). **Carrying costs** are defined as all costs associated with inventory investment plus storage costs, which might include interest, insurance, taxes, and storage expenses, among others.

KEY POINT . . .

All inventory management systems attempt to simultaneously maximize inventory turnover and minimize inventory carrying costs.

. . . SO WHAT?

There is a fine balance in respect to inventory control and quality. Order too little, and products will not be on the shelf when needed. However, order too much, and products will sit on the shelves unused and possibly go to waste. When inventory does not turn efficiently, it is a financial management concern and can affect the profitability and liquidity of the business. All pharmacy personnel should understand this fact.

ORDER BOOK

Many pharmacies use an order book system, also called a want list or want book. The order book is the simplest form of inventory control. When used as the sole method of inventory control, it is likely to lead to over- and under-ordering of inventory. The **order book** is a

simple order list—much like a home grocery shopping list. When pharmacists or pharmacy technicians identify a product that needs to be reordered, they simply write the item in the order book. The listed drugs are then ordered periodically from wholesalers or other suppliers.

Although this approach is simple, it provides the least amount of organized control of inventory, because it is highly dependent on the active staff participation. Individuals must note how much drug inventory remains on the shelf, remember how much is typically used over a specified time period, forecast a need for that drug, and place a request on the order book. It is common for individuals not to notice the need for a drug or to forget to note the need on the order book (causing an inventory shortage that is difficult to manage in the course of urgent or routine patient care, which, of course, can be embarrassing). However, even the most diligent and attentive individuals can make mistakes because the order list approach relies excessively on people's memories and individual discretion. Human fallibility can lead to active failures. A faulty memory or poor judgment can lead to running out of drugs or ordering too much. If too much is ordered, at best, it may reduce inventory turnover; at worst, it may remain unused on the shelf until it expires and must be discarded or returned to the supplier (i.e., inefficiency). Therefore, the order book system is usually not the sole method of inventory management and is often used in conjunction with one of the other systems mentioned previously.

PAR-LEVEL SYSTEMS

Par-level inventory systems are slightly more sophisticated than the order book. The par-level inventory system relies on a predetermined order quantity and an order point. **Par-level systems**, also known as minimum/maximum systems, are based on the principle that individual inventory drug use falls within a predictable range. The term *par-level* means within a standard range. If that range can be identified, then minimum and maximum order quantities can be set. Thus, a shelf-sticker is developed for each inventory product that identifies the minimum and maximum quantities of drug to be kept on hand. Shelf labels are placed on the storage bin or shelf to alert all staff to the minimum stock quantity (**Figure 12-5**). These shelf stickers act as a general guide for staff to avoid running short on a product or overstocking. In more sophisticated models where just-in time inventory quantity is maintained, a computerized database may be employed to manage a par-level system as opposed to shelf stickers and manual accounting. **Just-in-time inventory management** is a philosophy that simply means products are ordered and delivered at just the right time—when they are needed for patient care—with a goal of minimizing wasted steps, labor, and cost. Process engineers also use a Japanese term known as *kanban* (kän-bän) to describe the process of using a sign or a visual message to communicate when parts (in this case pharmaceutical inventory levels) are running low and have reached a reorder point in the process of manufacturing.¹⁷ When the inventory is reduced to or below the reorder point, designated pharmacy personnel initiate a purchase order or electronically transmit a purchase order to a drug wholesaler. In the case of automation, the robot may initiate the purchase order. The amount of drug ordered should be of a sufficient quantity to bring the amount to a level within the min-max range, but should generally not exceed the maximum level established. This par-level system frequently requires pharmacy staff to routinely scan inventory levels, often using a hand-held bar-code scanning device, who then place orders accordingly.

The par-level system can be managed either manually or electronically. Frequent reassessments of the par levels must be conducted to respond to the dynamic nature of patient medication needs. In the fully computerized inventory system, each dispensing transaction is subtracted from the **perpetual inventory** log that is maintained electronically; conversely, all products received are added to the inventory log. When the quantity



FIGURE 12-5. Shelf labels.

of a pharmaceutical product in stock reaches a predetermined par-level point, a purchase order is automatically generated to order more of the product. The system does not depend on any one employee to monitor the inventory or to reorder pharmaceuticals. The technology is available to have a computerized inventory in most pharmacies, but interfacing a computerized inventory system with existing pharmacy computer systems designed for dispensing and patient management is often difficult. In addition, other variables such as product availability, contract changes, and changing use patterns (either up or down), make relying on the fully computerized model challenging. Consequently, even the most sophisticated electronic or automated systems require careful human oversight and management.

ECONOMIC MODELS

Economic models of inventory control attempt to use economic and statistical methods to predict the need for drugs over time. One time-tested model is the **Pareto/ABC analysis**. The Pareto/ABC analysis is based on the 80/20 principles or *law of the vital few*. This theory states that approximately 80% of most problems can be attributed to roughly 20% of their potential causes. Applied to inventory control, the Pareto principle highlights the fact that a relatively small number of drugs account for a disproportionate amount of drug usage (and often times cost) in a health system. Thus, a Pareto ABC analysis essentially groups inventory products by aggregate value and volume of use into three groupings (A, B, and C). This analysis is useful in determining where inventory control efforts are best directed. For example, group A may include 10% of all items that make up 70% of the inventory cost. Tight control over these items would be sensible. Group B may include 20% of items and 15% of the inventory cost. An automatic order cycle might be useful here based on well-established par levels. Group C may include 70% of items and 10% of the inventory cost. Less aggressive monitoring of these items may be justifiable.

The **economic order quantity (EOQ)** model of inventory control is another method that attempts to minimize inventory holding costs and ordering costs. The EOQ approach (also known as the *minimum cost quantity approach*) decides inventory order quantities through the use of an accounting formula that calculates the point where the combination of order costs and inventory holding costs is minimized.

The exact details of the EOQ approach is beyond the scope of this chapter, but some details are relevant. EOQ relies heavily on the accuracy of various data inputs such as annual product usage, fixed costs associated with each order (e.g., processing the purchase order, receiving, inspection, processing the invoice, vendor payment, inbound freight costs), and the annual cost per average on-hand inventory unit. If calculated accurately, it results in the most cost-efficient order quantity. It can be argued that anytime one has repetitive purchasing tasks, EOQ should be considered. However, applying EOQ universally is relatively difficult in pharmacy practice because of the wide variability of the individual patient's pharmaceutical needs. Therefore, some pharmacies may find it valuable to use EOQ with a combination of the other systems mentioned here.

A sophisticated system for inventory management is an automated or computerized system that supports a just-in-time product inventory.¹⁸ Pharmaceuticals are neither overstocked nor understocked. The pharmacy's productivity "pulls" the inventory required into the system at just the right time. In pharmacy, this business philosophy couples responsible financial management of pharmaceutical purchasing with the clinical aspects of patient care. Of course, the effectiveness of a just-in-time inventory management system is highly dependent on the reliability of the supply chain before product reaches the pharmacy. There may be factors that impede effective inventory management that are outside of the control of the pharmacy and wholesale pharmaceutical distributor. Examples include supply chain defects caused by manufacturing issues (see Drug Shortages section that follows).

The use of automated dispensing devices in inpatient hospital nursing units, clinics, operating rooms, and emergency departments has facilitated the use of computers for inventory management. These devices are essentially repositories, or pharmaceutical vending machines, for medications that will be dispensed directly from a patient care area. A variety of manufacturers of automated dispensing devices are in the market today. The Pyxis Medstation and Omnicell suppliers are examples of products available to institutions today. These machines generally are networked via a dedicated computer file server within the facility, and they allow both unit dose and bulk pharmaceuticals to be stocked securely on a given patient care unit location. The machines are capable of tracking perpetual inventory at the product level. They also limit access to only authorized personnel, record the identities of those who access inventory, and record how much of a specific drug was removed for a given patient. A useful feature in many of these systems allows pharmacy personnel to automatically generate a fill-list of what needs to be replenished on the basis of a par-level system. In essence, the nursing and medical personnel who use these automated dispensing devices have a computerized inventory and billing system that the pharmacy staff manages. Medications used to restock these devices may be taken from the pharmacy's main inventory, or a separate purchase order may be executed for each device on a periodic basis.

KEY POINT...

The Pareto ABC method of inventory control is based on the 80/20 principles highlighting the fact that a relatively small number of drugs may account for a disproportionate amount of drug usage and expense.

...SO WHAT?

The 80/20 principles are useful in prioritizing almost any action in medicine, business, or other aspect of life. It is where one pays attention to the critical few as opposed to the trivial many. Knowing that focusing on the 20% of the things causing 80% of the variability associated with a problem can save time and improve performance.

DRUG QUALITY AND SECURITY ACT

In 2013, then President Obama signed into legislation the Drug Quality and Security Act (DQSA) to be phased in over a 10-year period. In that time, the DQSA interoperable electronic system will enable verification of a given drug product’s legitimacy at the package level, enhance the notification and detection capabilities associated with illegitimate (counterfeit) drug products, and facilitate more efficient drug product recalls.

It is expected that drug product manufacturers, wholesale distribution firms, and pharmacy practitioners will be called on to cooperate and collaborate with the U.S. Food and Drug Administration (FDA) in the development of the interoperable system.

Key provisions of Title II of the DQSA known as the *Drug Supply Chain Security Act* are summarized in **Table 12-2**. The consumer protection afforded through implementation will allow the FDA to minimize exposure to pharmaceuticals that are stolen, counterfeit, contaminated, or otherwise harmful as it effectively removes these dangerous products from the supply chain.¹⁹

DRUG RECALLS

A manufacturer, on its own or at the direction of the FDA, will occasionally recall pharmaceuticals for such reasons as mislabeling, contamination, lack of potency, lack of adherence to the acceptable Good Manufacturing Practices, or other situations that may present a

TABLE 12-2.
Proposed DQSA Requirements and Provisions¹⁹

Product identification	A unique product identifier (i.e., barcode) to be placed on certain prescription drug packages by manufacturers.
Product tracing	All those involved in the drug supply chain of custody to provide information about a drug and who handled it each time it was sold in the U.S. market.*
Product verification	Systems and processes to be developed that facilitate verification of the product identifier on certain prescription drug packages.*
Detection and response	All those involved in the drug supply chain of custody to quarantine and promptly investigate a drug that has been identified as suspect, meaning that it may be counterfeit, unapproved, or potentially dangerous.*
Notification	Systems and processes to be developed that facilitate notification of the FDA and other stakeholders if an illegitimate drug is found.*
Wholesaler licensing	The licensing status and contact information of wholesale drug distributors that is conveyed to the FDA and made publicly accessible.
Third-party logistics provider licensing	Logistics providers supporting the drug distribution process through intermediate storage logistical operations. This requirement will require them to be licensed at the state or federal level to facilitate the other requirements as currently stated.

* This includes manufacturers, wholesale drug distributors, and those who dispense (i.e., pharmacies).

FDA: U.S. Food and Drug Administration

significant risk to public health. The number of drug-related recalls has increased sharply since 2004, and the majority of these recalls were issued after 2012.²⁰ A pharmacy must have a system for rapid removal of any recalled products.⁶

ROLE OF THE U.S. FOOD AND DRUG ADMINISTRATION IN RECALLS

The FDA plays an active role in initiating the drug recall process. It coordinates drug recall information, helps manufacturers and distributors to develop specific recall plans, and performs health hazard evaluations to assess the risk facing the public by the recalled products. It also classifies recall actions in accordance with the level of risk and formulates recall strategies on the basis of the health hazard presented by the product in addition to other factors, including the extent of distribution of the product to be recalled. It decides on the need for public warnings and assists the recalling agency with public notification about the recall as needed.

The FDA publishes a weekly enforcement report that provides recalled product details,^{21,22} and some institutions subscribe to other services such as the ECRI Institute's *Alerts Tracker*TM.

Between June 2012 and December 2014, the FDA issued 21,120 recalls (all types). There were 3,045 pharmaceutical recalls, which accounted for 14% of the total. The five most common reasons for drug recalls during this period²⁰ were as follows:

1. Product contamination (50%)
2. Mislabeling (22%)
3. Adverse drug reaction (10%)
4. Defective product (7%)
5. Incorrect product potency (6%)

KEY POINT . . .

Pharmacies must have reliable systems in place to rapidly remove any recalled products. In fact, it is a duty associated with pharmacy practice.

. . . SO WHAT?

A responsive system of removing recalled products protects patients and saves time for pharmacy employees. Without a system to easily identify potentially unsafe drugs for removal from inventory, segregation, and return, patient care is put at risk and the dispensing pharmacist is liable if a defective (recalled) product reaches the patient and causes harm.

ROLE OF MANUFACTURER/DISTRIBUTOR IN RECALLS

Because of their responsibility to protect the public consumer, manufacturers or distributors typically implement voluntary recalls when a marketed drug product needs to be removed from the market. This method of recall is generally more efficient and effective in ensuring timely consumer protection than an FDA-initiated court action or seizure of the product. The manufacturer of the product or the drug wholesalers send the recall notices in writing to pharmacies. These notices indicate the reason for the recall, the name of the recalled product, the manufacturer, all affected lot numbers of the product, and instructions on how to return the product to the manufacturer. On receipt of the recall notice, a pharmacy staff member—usually a pharmacy technician—will check all pharmaceutical inventory stores to determine if any recalled products are in stock. If none of the recalled products are in stock, a note indicating “none in stock” is written on the recall notice and filed in a recall log to document that the recall was properly addressed. If a recalled product is in stock, all products should be gathered, packaged, and returned to the manufacturer according to the instructions on the recall notice. The **pharmacist in charge** (or appropriate

delegate) should review the package before returning it to the manufacturer. If patients have received a recalled product, the pharmacist in charge must take ethical actions guided by the institution's policies and procedures and professional code of conduct. On completion of all activity regarding the product recall, a summary of actions taken should be documented on the recall letter and filed for later access. The FDA has been known to request documentation of all recall activities to ensure compliance and, ultimately, patient safety. Pharmacy personnel should keep in mind that it may be necessary to order replacement stock to compensate for recalled items that were removed from stock. In some instances, the recall may encompass all possible substitution products, where it will be impossible to order replacement stock until the supply chain returns to its normal state.

The pharmacist in charge should be notified in this case because he or she will need to decide which, if any, alternative products may need to be placed into inventory as therapeutic alternatives to the out-of-stock items and should take appropriate measures to adjust the formulary and communicate accordingly.

DRUG SHORTAGES

Occasionally, manufacturers will be unable to supply a pharmaceutical because of various supply and demand situations. This may involve the inability of the manufacturer to obtain raw materials, manufacturing difficulties related to equipment failure, or simply the inability to produce sufficient quantities to stay ahead of the market demand for the pharmaceutical. Although unfortunate, drug shortages are a reality that must be dealt with to avoid compromising patient care. As with drug recalls, the pharmacist in charge should be notified so he or she can communicate drug shortages and recommend alternative therapies effectively to prescribers.

ORDERING AND BORROWING PHARMACEUTICALS

Pharmaceutical Purchasing Groups

Most health-system pharmacies are members of a **group purchasing organization (GPO)**.^{8,23} Health systems, hospitals, and ambulatory practices can join together in a purchasing group to leverage collective buying power and take advantage of any lower prices manufacturers offer to large groups that can guarantee a significant volume of orders over long periods of time (typically 1 or 2 years or longer). Contracts may involve sole-source or multisource products. *Sole-source products* (typically brand name drugs) are available from only one manufacturer, whereas *multisource products* (often generics or substitute products) are available from numerous manufacturers.

GPOs negotiate purchasing contracts that are mutually favorable to members of the group and to manufacturers. Members benefit from lower drug prices and reduced need for staff to spend time establishing and managing purchasing contracts with product vendors. Manufacturers benefit from a steady demand for products from the purchasing organization.

A typical contract works as follows: a GPO guarantees the price for pharmaceuticals over the established contract period. With the purchase price predetermined, the pharmacy can order the product directly from the manufacturer or from a wholesale supplier. Occasionally, manufacturers are unable to supply a given product that the pharmacy is buying on contract, which may require the pharmacy to buy or substitute a competing product not on contract at a higher cost. Most purchasing contracts will include language intended to protect the pharmacy from incurring additional expenses in the event this occurs. Generally, the manufacturer will be liable to rebate the difference in cost back to the pharmacy

when this occurs. Therefore, it is important that the pharmacy technician documents any resulting off-contract purchases and shares these with the pharmacist in charge for reconciliation with the contracted product vendor.

DIRECT PURCHASING

Direct purchasing from a manufacturer involves the execution of a purchase order from the pharmacy to the manufacturer of the drug instead of indirectly through a wholesaler. The advantages of purchasing direct rather than from a middleman include not having to pay handling fees to a third-party wholesaler, the ability to order on an infrequent basis (e.g., once a month), and a less demanding system for monitoring inventory. The disadvantages include the need to order larger quantities to take advantage of manufacturer discounts, the need for more capacity to store the additional inventory, more cash tied up in inventory, more complicated drug return and crediting, and the need to spend more time to prepare, process, and pay purchase orders to many different companies. Other disadvantages have to do with the likelihood that the manufacturer may be distant to the pharmacy, creating problems with longer lead times and product delivery.

For most pharmacies, the disadvantages of direct ordering outweigh the advantages. As a result, most pharmacies primarily purchase through a drug wholesaler under the terms and conditions of the prime vendor agreement established. Some drugs, however, can be purchased only directly from the manufacturers. These products generally require unique control or storage conditions. Consequently, most pharmacies will have a combination of direct purchases from manufacturers and drug wholesalers.

KEY POINT . . .

For most pharmacies, the advantages of purchasing from wholesalers outweigh the advantages of ordering direct from manufacturers.

. . . SO WHAT?

There is a misconception often promoted by advertisers that “buying direct” or “cutting out the wholesaler” saves money. However, when one considers the purchasing costs, carrying costs, and other operating expenses associated with ordering direct from a large number of suppliers, purchasing from wholesalers often provides greater value.

COMPOUNDING MANUFACTURERS

Title I of the DQSA is known as the Compounding Quality Act, and it clarifies certain conditions whereby certain compounded drug products are exempted from particular aspects of the Food, Drug and Cosmetics Act. Additionally, it created provisions for a compounder to become an *outsourcing facility*. Such facilities qualify for certain exemptions from FDA approval requirements, including the end-product labeling requirement concerning directions for use. However, it does not exempt outsourcing facilities from the requirement to follow FDA prescribed current *Good Manufacturing Practice* regulations, which are also expected of any pharmaceutical manufacturer.

As a result, those compounding manufacturers registered with the FDA as outsourcing facilities are subject to the FDA’s formal inspection, must meet other established FDA conditions such as prudent adverse event reporting, and must provide the FDA with information pertaining to the products compounded for distribution.²⁴ Prior to purchasing compounded drug products from an outsourced provider, the pharmacist in charge should be consulted. The FDA maintains a detailed online database entitled *Registered Outsourcing Facilities* that includes any disciplinary or corrective actions taken by the FDA through its enforcement of this regulation.²⁵

PROCURING SPECIALTY PHARMACEUTICALS

Although an industry-wide definition for the term *specialty pharmaceutical* is not readily apparent, the practice of handling these products has steadily become more commonplace. Historically these products were limited to a relatively small array of injectable products but now include oral products. Characteristics of specialty pharmaceuticals include use in the treatment of complex, chronic, and/or rare conditions; relatively high treatment cost (e.g., \$10,000–100,000 annually); restricted distribution channels; nuanced storage, handling, and/or administration requirements; as well as the need for close therapeutic monitoring (e.g., Risk Evaluation Mitigation Strategy in the interest of patient safety and drug effectiveness).²⁶

Considering the characteristics of this evolving drug subclassification, it stands to reason that *specialty pharmacies* have also evolved and focus solely on serving a more specialized patient population (e.g., those with autoimmune diseases such as multiple sclerosis, Crohn's disease, and rheumatoid arthritis; those with growth hormone disorders; cancer patients; those afflicted by HIV/AIDS/hepatitis C). Manufacturers frequently restrict the distribution of items considered to be specialty pharmaceuticals.

It is becoming commonplace for specialty pharmaceutical collaborations to exist among pharmacies and with drug manufacturers across the continuum of care. These collaborations are necessary to ensure high-quality patient access to specialty pharmaceuticals. Therefore, it is important that all pharmacists and technicians have a foundational understanding of *specialty pharmacy practice* as the purchasing and inventory control of specialty pharmaceuticals is likely to continue to be restrictive.²⁶

SECTION 340B OF THE PUBLIC HEALTH SERVICE ACT

Because of the strong implications related to pharmaceutical purchasing and inventory management for covered entities, section 340B of the Public Health Service Act (340B) is worth a mention in this chapter. In this context, *covered entities* is a term that includes organizations qualifying as disproportionate share hospitals or as Health Resources and Services Administration (HRSA) federal grantees under the Social Security Act.

The intent of the 340B program is to permit covered entities to “stretch scarce federal resources as far as possible, reaching more eligible patients, and providing more comprehensive services.”²⁷ The program requires drug manufacturers to discount medication provided to outpatients. In turn, this increases the financial stability of the covered entities and their ability to continue to serve vulnerable patient populations and reduces the financial burden on taxpayers.

This is a complex and beneficial program in which many pharmacies are able to participate. Those involved in the ordering, receiving, distribution, and recordkeeping associated with the 340B program should undergo formal training and follow established organizational procedures to ensure compliance with the regulatory nuances of the program.

DRUG WHOLESALER PURCHASING/PRIME VENDOR PURCHASING

Purchasing from a drug wholesaler permits the acquisition of drug products from different manufacturers through a single vendor. When a health-system pharmacy agrees to purchase most (e.g., 90% to 95%) of its pharmaceuticals from a single wholesale company, a **prime vendor agreement (PVA)** is established, and, customarily, a contract between the pharmacy and the drug wholesaler is developed. Usually, wholesalers agree to deliver a large proportion (i.e., 95% to 98%) of the items on an acceptable schedule and offer a 24-hour/

7-day-per week emergency services. They also provide the pharmacy with electronic order entry/receiving devices, a computer system for ordering, bar-coded shelf stickers, and a printer for order confirmation printouts. They may also offer highly competitive discounts, including those for prepayment. These wholesaler services make the prime vendor contracts appealing and result in more timely ordering and delivery, less time spent creating purchase orders, fewer inventory carrying costs, less documentation, computer-generated lists of pharmaceuticals purchased, and overall simplification of the credit and return process.

Purchasing through a prime vendor typically allows for drugs to be received shortly before use, supporting the just-in-time ordering philosophy mentioned earlier in this chapter. Purchasing from a wholesaler is a highly efficient and cost-effective approach toward pharmaceutical purchasing and inventory management. Many wholesale distribution firms offer value-added services such as a quarterly business review (QBR). In the QBR, the wholesaler's team representing the pharmacy's interests shares statistical and financial trends pertaining to the pharmacy's use of the wholesaler. This provides valuable information to the pharmacist in charge so that purchasing practices can be optimized under the PVA.

BORROWING PHARMACEUTICALS

No matter how effective a purchasing system is, there will be times when the pharmacy may need to borrow drugs from other nearby pharmacies. Most institutional pharmacies have policies and procedures addressing this situation. *Note:* Several state and federal laws limit the extent to which a pharmacy may serve in the same capacity as a licensed drug wholesaler. The process of a pharmacy loaning (or selling) pharmaceuticals outright to another agency that is legally permitted to purchase and own them requires careful consideration of these laws.

Borrowing or loaning drugs between pharmacies is usually restricted to emergency situations and limited to authorized staff. Borrowing is also limited to commercially available products, thus barring any borrowing of compounded products or investigational medications. Most pharmacies have developed forms to document and track borrowed or loaned merchandise (**Figure 12-6**). These forms also help staff document the details imperative to error-free transactions.

The pharmacy department's borrowing and loan policies and procedures should provide detailed directions on the process, which products may be borrowed or loaned, sources for the products, and reconciliation of borrow-loan transactions (the pay-back process). Securing the borrowed item may require the use of a transport or courier service or may include the use of security staff or other designated personnel. This information is vital for pharmacy personnel to understand and fulfill their responsibility when borrowing and loaning products.

PRODUCTS REQUIRING SPECIAL HANDLING

Most pharmaceuticals will be handled and processed in the inventorying and purchasing systems described above, with the exception of controlled substances, investigational drugs, compounded products, repackaged drugs, and drug samples.

Controlled Substances

Controlled substances have specific ordering, receiving, storage, dispensing, inventory, record-keeping, return, waste, and disposal requirements established under the law (see Chapter 8: Controlled Substances Management). *The Pharmacist's Manual: An Informational Outline of the Controlled Substances Act*¹⁰ and the *ASHP Technical Assistance Bulletin*

Children’s Hospital Colorado
13123 E. 16th Ave; B375
Aurora, CO 80045
Central: 720-777-6705
Buyer: 720-777-6012
DEA# FZ0#####

*****REQUIRED*****
**COMPLETE ALL LINES PER STATE
BOARD OF PHARMACY
REQUIREMENTS**

Date: _____		Time: _____	
Drug Name: _____		Strength: _____	
Dosage Form: _____		Qty: _____	NDC# _____

(check one) <input type="checkbox"/> Loaned To <input type="checkbox"/> Borrowed From		Your name: _____ (please print clearly)	
<input type="checkbox"/> Medical Center of Aurora 1501 S. Potomac Aurora, CO 80012 303-695-2630 BA5045681	<input type="checkbox"/> University Hospital 12605 E. 16 th Ave Aurora, CO 80010 720-848-1389 BU2203937	<input type="checkbox"/> Walgreens @CHCO 13123 E. 16 th Ave Aurora, CO 80012 720-626-4524 FW0619051	<input type="checkbox"/> Swedish Medical Center 501 E. Hampden Ave Englewood, CO 80113 303-788-4020 BS4782909
<input type="checkbox"/> Denver Health 790 Delaware St. Denver, CO 80006 303-602-9200 AC3360752	<input type="checkbox"/> Presbyterian/St. Luke’s 1719 E. 19 th Ave Denver, CO 80218 303-839-6781 BP4782860	<input type="checkbox"/> Sky Ridge MC 10103 Ridge Gate Pkwy Lone Tree, CO 80124 720-225-1100 BS8281278	<input type="checkbox"/> St. Anthony Hospital 11700 W 2 nd Pl Lakewood, CO 80228 720-321-8290 FS3079034
<input type="checkbox"/> CHCO South Campus 1811 Plaza Drive Highlands Ranch, CO 80129 Ext: 8-0108	<input type="checkbox"/> CHCO North Campus 469 West State Highway 7 Broomfield, CO 80023 Ext: 7-9345	<input type="checkbox"/> CHCO Briargate Campus 4125 Briargate Parkway Colorado Springs, CO 80902 Ext: 5-9302	<input type="checkbox"/> CHCO Uptown Campus 1830 Franklin St. Denver, CO 80218 Ext: 7-9345
<input type="checkbox"/> Other facility: _____			
Address: _____			
Phone: _____		DEA# _____	

Date Returned: _____		Returned by: _____	
Drug Name: _____		Strength: _____	
Dosage Form: _____		Qty: _____	NDC# _____

A CII DRUG MAY ONLY BE DISTRIBUTED UPON RECEIPT OF A PROPERLY EXECUTED DEAo 222 FORM

FIGURE 12-6. Borrow/loan form.

on *Institutional Use of Controlled Substances*²⁸ also provide detailed information on the specific handling requirements for controlled substances.

In some pharmacies, technicians work with pharmacists to manage inventory and order, dispense, store, and secure controlled substances. The pharmacy technician should know two principles regarding controlled substances:

1. Ordering and receiving Schedule II controlled substances requires special order forms and additional time (1 to 3 days) unless utilizing CSOS.
2. These Schedule II substances are inventoried and tracked continuously via a perpetual inventory process, whereby each dose or packaged unit is accounted for at all times.

Investigational Drugs

Investigational drugs also require special ordering, inventorying, and handling procedures. Generally, the use of investigational drugs is categorized into two distinct areas:

1. In a formal protocol approved by the institution.
2. For a single patient on a one-time basis that has been authorized by the manufacturer and the FDA.

In both cases, the physician may be responsible for the ordering, and the pharmacy staff handles the inventory management of the investigational drug.

Some pharmacies associated with academic centers or institutions conducting clinical research may have a pharmacist principally dedicated to pharmaceutical research activities manage the formally organized investigational drug services. In these cases, the investigational drug service pharmacist may be responsible for the ordering, dispensing, and inventory management of investigational drugs according to the research protocol.

Compounded Products

Compounded pharmaceuticals are another type of product handled by pharmacy personnel; unlike drugs ordered from an outside source, compounded products are extemporaneously prepared in the pharmacy as indicated by scientific compounding formulas and processes. These products may include oral liquids, topical preparations, solid dosage forms, or sterile products, among other dosage forms.

The use of these products requires that prescribing patterns and expiration dates be monitored closely because many compounded products have short shelf lives. Pharmacy technicians will likely be the ones charged with monitoring patient use of compounded drugs, product expiration dates, and additional stock needs. Pharmacy technicians may initiate compounding activities, but this may vary according to departmental procedures established in conjunction with applicable state and federal regulations governing pharmacy practice.

Repackaged Pharmaceuticals

Although manufacturers supply many drugs in a prepackaged unit dose form, the pharmacy staff is responsible for packaging some products. These items are generally unit dose tablets and capsules, unit dose oral liquids, and some bulk packages of oral solids and liquids. Each pharmacy establishes stocking mechanisms for these products and relies on pharmacy technicians to identify and respond to production and stock needs. Generally, designated technicians coordinate repackaging activities, but some pharmacies may integrate repackaging with other pharmacy technician responsibilities. Knowledge of the department's procedures for repackaging is required to prevent disruptions in dispensing activities.

Nonformulary Items

Nonformulary items also require special handling. No matter how much planning is devoted to formulary management, some patients will legitimately need medications not routinely stocked in the pharmacy. The pharmacist usually determines when a nonformulary medica-

tion should be ordered into stock. However, the pharmacy technician is often in the best position to monitor the supply and determine when and if additional quantities should be ordered. Nonformulary medications generally are stored separately from formulary products and have separate inventory mechanisms. Manual tracking mechanisms and computer system queries of active nonformulary orders are the two most common techniques used to monitor and order these products.

Medication Samples

Storage and use of medication samples in institutions are controversial and require special handling procedures. Traditional inventory management and handling practices do not work well with medication samples for two reasons. *First*, medication samples are not typically ordered by the pharmacy; they are generally provided free of charge by the drug manufacturer to the physicians upon formal request. This often occurs without the knowledge of pharmacy personnel. *Second*, the pharmacy does not usually dispense samples. These factors make it difficult to know whom to contact if a medication sample is recalled and to ensure that medication samples are not sold. Because of difficulties in controlling samples, organizations may allow samples to be stored and dispensed in ambulatory clinics only after being registered with the pharmacy for tracking purposes. These difficult logistical and control factors have led many organizations to adopt policies that simply disallow medication samples altogether.

If an organization allows samples, they will probably be stored outside the pharmacy; pharmacy personnel will be required to register and inspect the stock of medication samples. Pharmacy technicians are sometimes involved in inspecting medication sample storage units. These technicians are often responsible for determining if a sample is registered with the pharmacy, stored in acceptable quantities, labeled with an expiration date that has not been exceeded, and, generally, stored under acceptable conditions.

KEY POINT . . .

The logistical control and disposal problems associated with medication samples have caused many pharmacies to simply prohibit their use in institutions.

. . . SO WHAT?

Samples are not “free”—manufacturers spend tremendous marketing dollars annually in this regard. Samples encourage use of new, more expensive drugs for patients—often in opposition to pharmacy efforts to provide the most effective medications to patients. Samples also require a separate inventory control and distribution system that adds to pharmacy personnel and overhead costs.

PROPER DISPOSAL AND RETURN OF PHARMACEUTICALS

Expired Pharmaceuticals

The most common reason drugs are returned to the manufacturer is because they are expired. Each year, approximately 2% of all drugs shipped to pharmacies are returned to the manufacturer.²⁹ Of those products returned, 72% are either outdated or short-dated.³⁰ The process for returning drugs in the original manufacturer packaging is relatively simple and not particularly time-consuming when done routinely. Returning expired products to the manufacturer or wholesaler prevents the inadvertent use of these products while enabling the department to receive either full or partial credit for them. Some wholesalers limit credit given on returns of short-dated products. Generally, wholesalers will not give

full credit on returns of products that will expire within 6 months. To return products, pharmacy personnel must complete the documentation required by the product's manufacturer or wholesaler and package the product so it can be shipped. Many wholesalers have implemented electronic documentation systems to further simplify the return process.

Technicians often perform these duties under the supervision of a pharmacist. Some pharmacies contract with an outside vendor who completes the documentation and coordinates the return of these products for a fee. In that case, the pharmacy technician need only assist the returned goods vendor with the location and packaging of expired pharmaceuticals.

Pharmaceuticals compounded or repackaged by the pharmacy department cannot be returned and must be disposed of after they have expired. Proper disposal prevents the use of sub-potent products or products without guaranteed sterility. The precise procedure for disposal depends on the type and content of the product. Some products, such as expired repackaged solids, can be disposed of using the general trash removal system, whereas others (e.g., expired compounded cytotoxic products) must be disposed of according to hazardous waste removal procedures. Each pharmacy has detailed procedures for hazardous waste removal, and pharmacy personnel should be familiar with these procedures. The pharmacy technician's disposal of expired compounded or repackaged pharmaceuticals should be completed under the supervision of the pharmacist.

Other products requiring disposal rather than return are chemicals used in the pharmacy laboratory. Most pharmacies will stock a supply of chemical-grade products used in extemporaneous pharmaceutical compounding. Examples of chemical products include sodium benzoate or sodium citrate (preservatives), lactose or talc (excipients), buffers, and active ingredients such as hydrocortisone, triamcinolone, neomycin, or lidocaine powders. These, along with all pharmaceuticals, should be disposed of in accordance with the applicable state or federal hazardous waste management regulations.^{2,3}

Expired controlled substances are disposed of uniquely. These products may not be returned to the manufacturer or wholesaler for credit. They must be destroyed in accordance with the applicable state or federal regulations, and the destruction must be documented to the satisfaction of the DEA.^{2,3,10} The DEA provides a specific form, Registrant's Inventory of Drugs Surrendered (Form 41), for recording the disposal of expired controlled substances (available at www.FDA.gov). Ideally, the actual disposal of expired controlled substances should be completed by a company sanctioned by the DEA or by a representative of the state board of pharmacy. In other cases, the DEA may allow the destruction of controlled substances by a pharmacy provided the appropriate witness process is followed and documented. The DEA disposal of controlled substances form should be completed properly and submitted to the DEA immediately after the disposal. A copy of the record of disposal form will be signed by a DEA representative and returned to the pharmacy, where it is kept on file. Previously, the DEA allowed for shipment of expired controlled substances and the completed disposal form to the regional DEA office, but this practice is no longer permitted.

The disposition of expired investigational drugs must also be documented carefully. Expired investigational drugs should be returned to the manufacturer or sponsor of an investigational drug study according to the instructions they provide. Investigational drug products that expire because of product instability or sterility issues should never be discarded. These doses should be retained with the investigational drug stock and be clearly marked as expired drug products because the investigational study sponsor will need to review and account for all expired investigational drug products.

Pharmaceuticals that need to be returned because of an ordering error require authorization from the original supplier and the appropriate forms. The Prescription Drug Marketing Act mandates that pharmacies authorize and retain records of returned pharmaceuticals to prevent potential diversion of pharmaceuticals. The pharmacy personnel must be familiar with pharmacy department procedures for returning medications to a supplier. Typically, a pharmacy will have a process for returning misordered medications to the prime drug wholesaler on a routine basis, which prevents the need for storage in the pharmacy of overstocked or misordered products. The pharmacy technician may be responsible for relevant documentation, filing paperwork, and packaging returned products under the supervision of the pharmacist.

■ ■ ■
SUMMARY

Figure 12-7 summarizes the main issues covered in this chapter. A wide variety of drugs requiring unique handling procedures are purchased and stored in institutional pharmacy inventories. These include controlled substances, investigational drugs, and non-formulary medications. Inventory of these drugs is managed with one or more forms of inventory control, from the simple (order book) to the complex (EOQ). Drugs are purchased directly from companies or indirectly through wholesalers in most cases, although they are sometimes borrowed from other pharmacies in emergency situations. The movement of pharmaceuticals into and out of the pharmacy through purchase, borrowing, recall, or expiration requires an organized, systematic, and cooperative approach. Each pharmacy staff member plays a role in the management of his or her pharmacy's system.

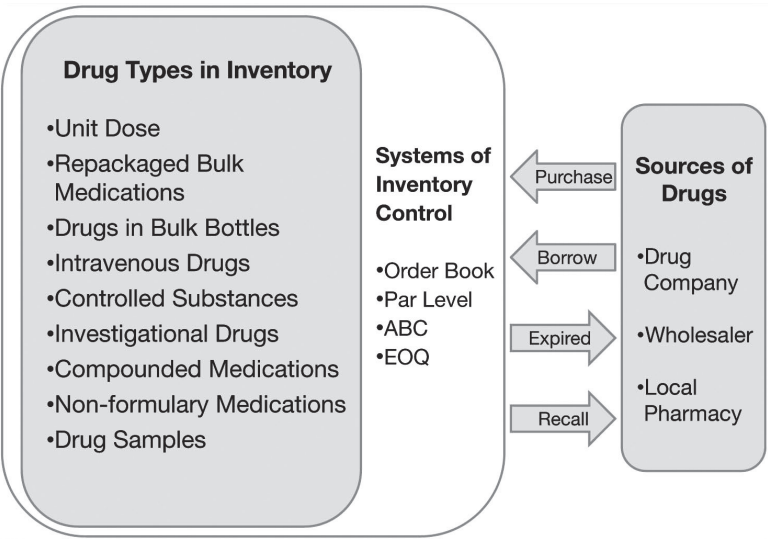


FIGURE 12-7. The medication purchasing and inventory system.

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CHAPTER REVIEW QUESTIONS

1. The _____ is developed and maintained by the P&T committee and is the cornerstone of the purchasing and inventory control system.

Answer: The answer is formulary. The formulary determines what is purchased and stored in pharmacies. An overly lenient formulary leads to a large number of products to be purchased and inventoried. This leads to greater inventory carrying costs and less efficient use of inventory.

2. Pharmacies frequently require that medications received from suppliers have a minimum shelf life of _____ remaining before the medications expire.
- 2 years
 - 1 year
 - 6 months
 - 1 month

Answer: c. 6 months. Actually, the answer to this question is dependent on the policies of each individual pharmacy. Six months is a good answer because it allows enough time for pharmacies to use the drug, but still allows suppliers to use up their supply of medications with longer expiration dates.

3. The public law enforced by the U.S. EPA that creates the framework for the proper management of hazardous and non-hazardous solid waste produced through pharmacy practice is known as _____.

Answer: Resource Conservation and Recovery Act (RCRA). The U.S. Environmental Protection Agency (EPA), and in many cases the state's hazardous waste regulatory agency, enforces hazardous waste laws. In the context of handling and disposal, numerous pharmaceutical products are considered to be hazardous wastes. Full compliance with these regulations is essential to avoid state and federal sanctions.

4. If total pharmaceutical purchases for the fiscal year (FY) ending 2016 total 10 million dollars and the physical inventory value on 12/31/2016 was 1 million dollars, the calculated inventory turns for FY2016 would be _____.
- 5
 - 10
 - 15
 - 20

Answer: b. 10 (\$10 million/\$1 million = 10).

5. According to the Institute of Medicine, *quality* is defined across six dimensions including:
- Product, place, price, promotion, people, pharmacy
 - Safety, efficiency, effectiveness, equity, patient-family centeredness, and timeliness
 - Objectivity, diversity, causality, eventuality, relativity, plausibility

Answer: b. Safety, efficiency, effectiveness, equity, patient-family centeredness, and timeliness. Effective pharmacy purchasing and inventory control measures are essential to fulfilling this ideal. As fundamental elements of the medication-use system, they support these aims of quality in healthcare.

6. Which of the following systems of inventory control system is also known as the maximum/minimum method of inventory control?

- a. Order book
- b. Par-level
- c. Pareto ABC analysis
- d. EOQ approach

Answer: b. Par-level. The par-level inventory system sets minimum and maximum order quantities based on the principle that individual inventory drug use falls with a predictable range.

7. Voluntary recalls of products initiated by the FDA are more efficient and effective in ensuring timely consumer protection than FDA recalls or seizures initiated through court action.

- a. True
- b. False

Answer: a. True. Recalls initiated by the courts are slow and costly. That is why active participation by pharmacists in voluntary recalls is essential for ensuring the safety of patients and the drug distribution system.

8. In the context of pharmacy supply chain management, the term *specialty pharmacy* implies specialists practicing possess unique knowledge, skills, and abilities necessary to maximize the timeliness, effectiveness, and safety of prescribed drugs.

- a. True
- b. False

Answer: b. True. *Specialty pharmacies* have evolved to serve a more specialized patient population (e.g., those with autoimmune diseases such as multiple sclerosis, Crohn's disease, and rheumatoid arthritis; those with growth hormone disorders; cancer patients; those afflicted with HIV/AIDS/hepatitis C).

9. _____ contracts are agreements between a health-system pharmacy and a wholesaler where the pharmacy agrees to purchase most of its pharmaceuticals from a single wholesale company.

Answer: Prime vendor. Prime vendor contracts give the pharmacy better drug prices, terms of drug delivery, and support services in return for using a single wholesaler for most purchases.

10. Other than antineoplastics, controlled substances, investigational products, and hazardous chemicals used in compounding, it is a generally acceptable practice to dispose of pharmaceuticals through a sanitary sewer or waste receptacle intended for landfill.

- a. True
- b. False

Answer: b. False. The EPA and some state health departments have established protocol governing the proper waste stream disposal of pharmaceuticals. Full compliance with these regulations is essential to avoid state and federal sanctions.

CHAPTER DISCUSSION QUESTIONS

1. How do hospital formularies influence the process of inventory control?
2. How does a hospital formulary differ from a formulary seen in community pharmacy settings?
3. Which of the six *dimensions of quality* can pharmacy staff members influence to the greatest degree in the context of managing pharmaceutical inventory?
4. What is the intent of HRSA's 340B program?
5. Compare the advantages and disadvantages of order book, economic model, and just-in-time inventory management systems.

Basics of Financial Management and Cost Control

Andrew L. Wilson

LEARNING OBJECTIVES

After completing this chapter, readers should be able to:

1. Identify the role of pharmacists in financial management of institutional resources.
2. Define key financial terms.
3. Describe the pharmacy and hospital budget process and the different budget components that comprise a pharmacy budget.
4. Discuss the purpose of productivity measurement and benchmarking in controlling operating costs.

KEY TERMS AND DEFINITIONS

- **Accounting:** A standard method for reporting the expenses, revenues, and accumulation of assets as well as other financial results.
- **Acuity:** Variations in the healthcare needs of a patient based on his or her severity of illness.
- **Assets:** The real, intangible, and financial items that are owned by the health system.
- **Balance sheet:** A financial statement that lists the wealth of the institution at a specific point of time.
- **Budget:** A plan for future expenses and revenue, typically over a 12-month period.
- **Capital budget:** The part of the budget usually comprised of items that cost more than a fixed threshold (e.g., an expense >\$5,000) and have a useful life greater than 5 years.
- **Capital expense:** Costs of a physical improvement or a piece of equipment that will provide benefit over a number of years. Capital expenses are generally significant in size and scope.
- **Case mix index (CMI):** An indicator of the average diagnosis-related group weight for all patients at an institution.
- **Case rate:** A negotiated payment that is based on a diagnosis-related group, a per diem (daily) amount, or other benchmark method to determine the hospital's payment. The hospital receives the case rate payment for the complete patient care episode, irrespective of the individual charges posted to the patient's account.
- **Chief executive officer (CEO):** The highest ranking executive in a health system, in charge of the total management, making the major corporate decisions.
- **Chief financial officer (CFO):** A corporate officer primarily responsible for managing the financial risks of a corporation.
- **Diagnosis-related group (DRG):** A system to classify hospital cases into one of approximately 500 groups, also referred to as DRGs, expected to have similar hospital resource use. The patient's primary diagnosis is typically the basis for payment.
- **Direct expense:** Expenses that are incurred by the pharmacy to deliver services and products.

- **Double entry bookkeeping:** A bookkeeping technique of entering a transaction on both sides of the balance sheet (as a debit on one side and a credit on the other) to keep income and expenses balanced.
- **Equity:** The net of assets and liabilities; also called net worth.
- **Expense:** A payment made by the health system to others for value received.
- **External benchmarking:** A process of measuring costs, services, and practices and comparing them to the organization's peers or to industry leaders.
- **Fixed expense:** A category of direct expense that does not vary significantly in the short-term with the volume of activity.
- **General ledger:** A detailed record of each financial transaction of the hospital.
- **Income statement:** A statement that lists the revenue, expense, and profit (or loss) of the institution over a period of time.
- **Indirect expense:** Payments for services that support the pharmacy but are not directly paid by the pharmacy; also called overhead.
- **Internal benchmarking:** The process of measuring costs, services, and practices against the organization's prior performance.
- **Liabilities:** The debts (i.e., unpaid bills) the hospital owes to creditors, loans, and bonds issued.
- **Operating budget:** The part of the budget that represents a forecast of the daily expenses required to operate the pharmacy.
- **Return on investment (ROI) or return on equity (ROE):** A mathematical model that measures how effectively funds invested in the firm by its owners or stockholders have been used.
- **Revenue:** Money received for products or services provided to customers.
- **Time and motion study:** A review of the activities and resources required to produce a good or service. A time and motion study is used to determine the resources necessary to complete a task or set of tasks and can be the basis to set goals for improvement or change.
- **Variable expense:** A category of direct expense that varies in the short term with the level of activity.
- **Variance:** The difference between the budgeted amount and the actual amount spent for a period, typically a month or for the fiscal year to date.
- **Volume budget:** The number of admissions, patient days, CMI, outpatient visits, emergency department visits, and other activities. The volume budget is prepared by the CFO and is the basis for budget calculations.
- **Work volumes:** Work units and paid hours that are generally used to describe pharmacy work volume. Health-system pharmacy workload volume may include prescriptions filled, orders processed, or doses dispensed and combinations of these components.



INTRODUCTION

Financial management and cost control are key activities for pharmacists in leadership roles in institutional practice. The high cost of pharmaceuticals and high pharmacist salaries, combined with the compelling need for pharmacy services and medication therapy in hospital care, requires thoughtful, cost-conscious management to ensure success. The growth of support systems and technology to manage medication-use process safety and effectiveness, including automation and information systems, add to the scope of financial management and cost control responsibilities of pharmacists. Pharmacy directors and

managers encounter tension between their patient care leadership and their management roles as they work to balance costs, benefits, and patient care outcomes in delivering pharmaceutical care. A working knowledge of financial management is essential to ensure that high quality pharmacy services are effectively delivered, and that the patient care mission of the pharmacy and the hospital are carried out optimally.

Pharmacists in hospitals are charged with developing and maintaining a medication-use system that provides the highest quality of care and serves the patient's medical and pharmaceutical needs to their fullest. However, in a healthcare delivery system where resources are finite, the pharmacy leadership role requires monitoring, prioritizing, and actively managing pharmaceutical and professional resources to use them to their greatest advantage. Building working relationships with administration, physicians, nurses, and others is based on an understanding of key relationships in cost management and finance. **Figure 13-1** is a schematic representation of the financial relationships and key terms, which underlie the discussion later in the chapter. In some instances, resource limitations and the balance between cost and benefit for pharmacy services and medication therapy may not be well-defined by senior hospital management or medical staff leadership, adding the burden and the opportunity to develop a broader, financially responsible plan for the hospital or health system to the pharmacy director.

An active, engaged pharmacy director is well-versed in clinical and professional disciplines surrounding medication use and pharmaceutical care. The director also possesses a keen understanding of the financial and productivity performance for his or her areas of responsibility and works to understand the role of the pharmacy service in the context of the institution. A knowledgeable pharmacy manager works to communicate the impact of pharmacy services and medication therapy, and secure the necessary resources to accomplish these goals. Audiences and forums for these discussions include the medical staff in pharmacy and therapeutics (P&T) committee meetings and other discussions, and senior hospital leadership in budget review and other administrative meetings. Because of the scope, magnitude, costs, and outcomes associated with medication therapy, health-system boards of trustees and corporate leaders rely on pharmacists to contribute to understanding

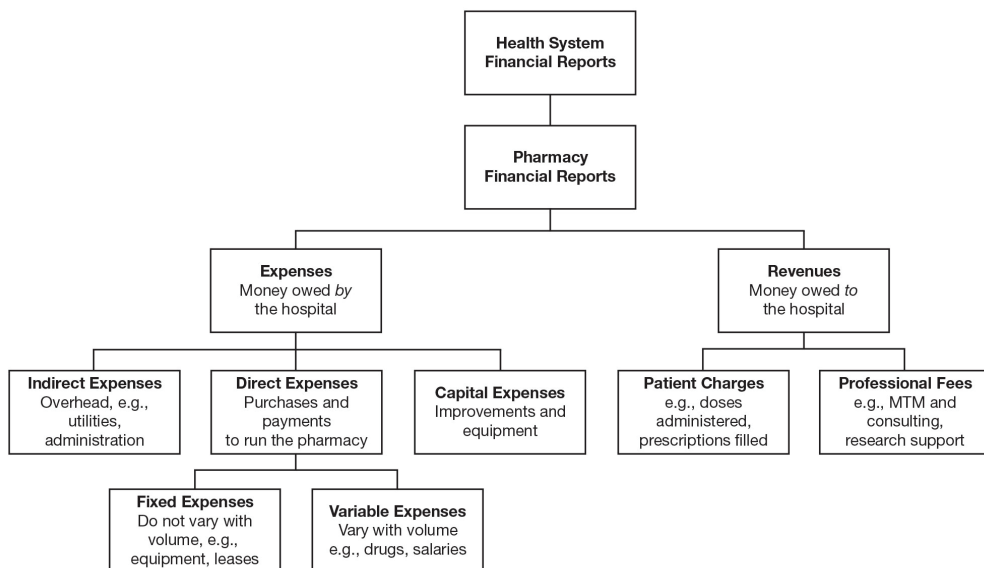


FIGURE 13-1. The financial structure of a health-system pharmacy.

the impact of medication costs. Increasingly, a key role of pharmacy leadership is to articulate a coherent plan for clinical pharmacists and other pharmacy staff to understand the balance of cost, benefit, and outcome in their daily professional decision-making.

Thoughtful financial management and cost control strategies allow institutional pharmacy directors to ensure that their department receives appropriate resources to meet patient care needs and the organizational mission. The controls and reporting mechanisms, which the institutional and pharmacy leadership put in place and maintain, ensure that these goals are met and that patient care quality and outcomes are optimized.

This chapter presents the basics of financial management in institutions for pharmacy students and newly practicing pharmacists. The purpose is to provide them with a sufficient understanding of financial principles to let them participate in management and leadership decisions that impact the success of the pharmacy practice. This chapter is presented in the belief that pharmacists and other pharmacy employees should see themselves as professional leaders

and partners with hospital administration, rather than hired employees. If pharmacists understand financial concepts such as revenue, profit, and expense and incorporate them into their decision-making and professional work, they will make better decisions that have a positive impact on the long-term viability of the pharmacy and the institution. Pharmacists who participate as partners are encouraged to be more engaged in managing the pharmacy and more accountable for providing efficient distribution and clinical services.

KEY POINT . . .

Pharmacists and other pharmacy employees should see themselves as partners with management, rather than hired employees. Understanding the financial management objectives of the institution provides them with insight to participate as partners.

. . . SO WHAT?

Many pharmacists have only modest interest in the management of pharmacy finances. Indeed, some even take an adversarial stance toward management: "They are just paper pushers and bean counters! They have no idea what it is like to provide direct patient care!" However, all pharmacy employees have some responsibility in managing the organization's resources written into their job descriptions and expectations of performance. Understanding financial management objectives and terminology helps employees meet their responsibilities.

PRACTICE STANDARDS

ASHP practice standards and guidelines refer to the leadership responsibilities of pharmacists and identify key roles and responsibilities related to financial management of a pharmacy service¹⁻³:

- **Financial management** — The pharmacy executive manages the health-system pharmacy's financial performance within the context of the broader health system. He or she develops budgets aligned with organizational and departmental objectives and monitors financial performance appropriately, performing financial audits and analysis as needed to ensure accurate, appropriate, and timely recording and classification of actual revenue capture and expenses.
- **Workload and productivity management** — Oversight of workload and financial performance should be managed in accordance with the health system's require-

ments. Management should provide for the determination and analysis of pharmacy service costs, capital equipment costs, and new project growth.

- **Financial performance** — A process shall exist to routinely monitor and document workload and financial performance. Metrics should encompass the full scope of patient care services provided by pharmacists and the pharmacy enterprise. This process should provide for the determination and analysis of hospital and system wide costs of medication therapy.
- **Financial decisions** — The pharmacy executive evaluates medication expenditure patterns and reimbursement trends, including the potential development of value-based approaches to pharmaceutical reimbursement. He or she seeks opportunities to implement medication-related services that can improve the financial health of the organization

Processes should exist for routine verification of patient healthcare insurance benefits and for counseling patients about their anticipated financial responsibility for planned medication therapies. A process should also exist for providing pharmacy support to uninsured, underinsured, and medically indigent patients.

FINANCIAL TERMS

Medical terminology is precise, and so is financial terminology. Pharmacists are trained to value thoughtful, direct, and evidence-based evaluations of medications, procedures, policies, and programs. They work to communicate professional assessments and directions in a precise manner to ensure that appropriate actions are undertaken. Leadership colleagues of pharmacists, including the institution's **chief executive officer (CEO)** and **chief financial officer (CFO)**, use similar precision in descriptions of the financial and operational performance of the hospital. Pharmacists need to embrace these financial terms, concepts, and metrics when describing the financial performance of the pharmacy service.

Financial terms and performance expectations must be understood within the context and goals of each institution. For-profit hospitals; not-for-profit hospitals; HMOs; integrated health systems; and state, federal, and other types of institutions each have different financial goals, reporting needs, and management structures. A pharmacist must learn the full meaning and implications of each of these terms in the context of their organization. The use and importance of each term will vary with the goals of the institution and the organization's financial status. Key terms to understand in all types of organizations are defined in the following discussion.

Expense

An **expense** is a payment made by the health system to others for value received. Pharmacy expenses fall into several categories: **direct expenses** are those incurred by the pharmacy to deliver services and products. *Supplies* are the largest category of direct expense, predominately pharmaceuticals. Other categories of supplies managed by pharmacy include blood products, intravenous (IV) fluids, syringes and needles, administration sets, and non-patient care supplies such as packaging materials, paper, labels, and other office supplies. *Human resources* are generally the second largest category of direct expense. Human resource expenses consist of the salary and benefit costs for pharmacists, pharmacy technicians, pharmacy managers, and others. Other direct expenses incurred by the pharmacy include the following:

- Leases for hardware and software to manage medication delivery including automated medication cabinets, dispensing robots, pharmacy computer systems, and IV pumps.

- Services including hood certification, service agreements for technology and equipment, and maintenance and repairs for pharmacy facilities.
- Professional education and development expenses including meetings, travel, and competency programs.
- Licenses, taxes, and other fees associated with accreditation, including pharmacy residency program accreditation.

Direct expenses can be further classified as fixed or variable. **Fixed expenses** are defined as costs that do not vary significantly in the short term with the volume of work. Property and equipment are examples; their cost does not change as the number of prescriptions filled rises and falls. **Variable expenses** are costs that vary in the short term with the level of activity. Purchase costs for pharmaceuticals are an example; costs rise and fall as the number of patients served and the number of prescriptions filled change. Pharmacy work volume may be counted based on the number of patient days, prescriptions or orders processed, or as the number of doses dispensed. Most health-system budgets base variable expense budgets for pharmacy supply and manpower on a combination of inpatient days, emergency department visits, and clinic visits or other ambulatory volumes.

Indirect expenses are payments for services that support the pharmacy but are not directly paid by the pharmacy. These include housekeeping, heat and air-conditioning, electricity, hospital administration salaries, hospital purchasing services, information systems support, the human resources department, the hospital finance department, and others. The cost of these indirect services is also referred to as *overhead*. In the modern health system, the magnitude of these costs is substantial. Because indirect expenses are beyond the control of the pharmacy manager, they are not generally a part of regular financial reports. However, indirect costs are considered when business plans and profitability of a service or program are reviewed, including pharmacy services.

An additional expense category in which a pharmacy service is increasingly involved is capital expenses. **Capital expenses** are defined as the cost of a building improvement or a piece of equipment that will provide benefit over a number of years. Health systems budget and manage capital expense separately from regular operating expenses. Accounting methods allow capital expenses to be spread across several years. Capital expenditures are typically significant in size and scope. Pharmacy examples of capital expenses might include new IV admixture hoods, remodeling of a pharmacy, or building a new pharmacy satellite. Health systems typically specify a financial test (e.g., an expense >\$5,000) and a duration of useful life of the purchase (e.g., >5 years) to identify an item or project as a capital expense.

KEY POINT . . .

The magnitude of indirect expenses is substantial in institutions but generally beyond the control of the pharmacy manager.

. . . SO WHAT?

Pharmacy departments share the expenses of many facilities and supportive services with other departments in institutions, although pharmacists have little influence on these expenses. These indirect expenses are a cost of doing the business of pharmacy and should be considered when conducting cost-benefit analyses and return-on-investment calculations for new pharmacy programs or other major spending.

Revenue

Revenue is defined as money received for products or services provided to customers. Pharmacy revenues consist primarily of *patient charges*. Patient charges may result from doses administered in an inpatient setting or from prescriptions dispensed in an outpatient pharmacy. Pharmacies may also generate revenue by providing professional services including consultation, management of research studies, education and other support services, and medication therapy management (MTM).

Inpatient pharmacy revenues appear on patients' hospital bills as charges. A total of all charges posted by the pharmacy to all bills for an accounting period (e.g., a month) are reported as the pharmacy's *gross revenue*.

Although charges for medications and pharmacy services are a focus for pharmacy managers, they are typically not the payments received by the hospital. Most inpatient care is paid at a case rate. A **case rate** is a payment that is negotiated based on a **diagnosis-related group (DRG)**, a per diem (daily) amount, or other benchmark method to determine the hospital's payment. The hospital receives the case rate payment for the patient's care, irrespective of the individual charges posted to the patient's account. Some hospital contracts pay a discounted percentage of billed charges, and most payers provide supplemental payments for patients whose care substantially exceeds the negotiated amount. However, almost no payer, including the federal government, pays full charge. Patients without insurance often are unable to pay their hospital bill, requiring the hospital to "write off" all or part of their bill, considering the cost of care as a charitable loss.

The case rate payment method is designed to encourage hospitals to provide care economically. It also allows the hospital to be the beneficiary of savings and efficiencies that it develops or to incur the cost of inefficient care delivery. Although this approach works well in theory, it creates challenges for pharmacy managers in understanding the impact of therapy selection and the management of the medication-use process. Because case rates are diagnosis-specific, diagnoses where medications are a significant expense are of the greatest financial and cost control interest to pharmacists. Formulary decisions, practice guideline development, and therapeutic decisions at the bedside may have a significant impact on the health system's ability to meet financial objectives treating these patients. This is discussed later in the chapter.

When the hospital receives payment for services, the case rate based payment is matched to the charge-based patient bill, and the "discount" is calculated and subtracted; the resulting payment is the *net revenue*. The net revenue consists of the gross revenue minus the discounts resulting from case rate-based payment. The hospital's accounting system allows the deductions from the gross revenue to be applied to the charges posted by the pharmacy and other departments. The resulting adjustment determines the net revenue to each department. The pharmacy's overall net revenue is calculated by subtracting the pharmacy's share of discounts, contractual allowances, and nonpayment for all patient bills to the hospital from the pharmacy gross revenue.

Outpatient prescriptions are typically charged in the same fashion. The pharmacy contracts with a third party (insurance provider, state Medicaid program, or pharmacy benefits manager [PBM]) to fill prescriptions at a fixed rate based on medication costs and service fees. Rate structures are typically based on a percentage of average wholesale prices for the medication plus a filling fee. Outpatient prescription payment methods are typically handled electronically at the time of dispensing; generally referred to as *adjudication at the point of service*. Each prescription claim is electronically verified and payment posted through access to a centralized information system. These systems provide recordkeeping and revenue tracking systems for outpatient pharmacy in real time.

Assets

Assets are the real, intangible and financial items that are owned by the health system. These include land, buildings, equipment, and the value of inventory. Assets also include cash, accounts receivable (unpaid bills owed by patients, insurance companies, and others) for services delivered but not yet paid. In the case of pharmacy, the majority of assets of interest are equipment and the inventory of drugs and supplies. Assets are offset by **liabilities**, the debts (unpaid bills the hospital owes to creditors, loans, bonds issued) owed against them. The net of assets and liabilities is equal to the **equity** held by the institution. In a for-profit organization, equity is a form of liability representing what the corporation owes to the stockholders.

Work Volumes

The amount of work done by pharmacies is represented by **work volumes**. Work volumes consist of a sum of the work units accomplished by the pharmacy such as the number of orders processed, number of doses dispensed, number of consults completed, or number of patient counseling sessions completed. The total hours paid for pharmacy employees is also a volume measure. Work volume for a hospital is generally reported as adjusted discharges or patient days. Health-system pharmacy workload calculations may use a denominator of patient counts such as inpatient admissions or discharges and a numerator of prescriptions filled, orders processed, or doses dispensed and combinations of these components to describe pharmacy workload. Typical indicators for pharmacy workload are adjusted using **case mix index (CMI)** or another indicator of patient **acuity** to recognize the additional cost and resources required to care for sicker patients. Outpatient pharmacy workload is generally reported as prescriptions filled and may include patient counseling, MTM, prior authorization for specialty drugs, and other direct patient care activities. Institutional pharmacy workload should also be adjusted to reflect the significant amount of effort and cost required to support outpatient surgery, emergency department activity, outpatient infusion services, and other areas that are not reflected in patient day or inpatient discharge count.

As pharmacy has evolved from a primary focus on medication dispensing to include more substantial clinical and cognitive services, workload models based on doses charged or doses dispensed have fallen out of favor. Workload models based solely on medication doses handled do not reflect the full range of pharmacy service activities, and their use is discouraged.

Healthcare Institution Accounting Methods

Accounting is a standard method for reporting the expenses, revenues, and accumulation of assets as well as other financial results. An institution maintains a balance sheet that lists its assets, liabilities, and equity. The **balance sheet** is a financial statement that lists the wealth of the institution at a specific point of time. Traditionally, assets appear on the left side and liabilities on the right; the two must be in balance. The balance sheet is described by the equation:

$$\text{Assets} = \text{Liabilities} + \text{Equity}$$

Double entry bookkeeping ensures that both sides of the equation remain balanced at all times. **Double entry bookkeeping** enters any transaction on both sides of the balance sheet (as a debit on one side and a credit on the other) to keep the equation balanced. As an example, a purchase of an IV hood creates a liability but creates an asset of equal value. **Table 13-1** is a simplified example of a balance sheet for a health system.

The second part of an organization's periodic financial review is the income statement. The **income statement** lists the revenue, expense, and profit (or loss) of the institution

TABLE 13-1.

Hospital Balance Sheet

Balance Sheet Community Hospital June 30, 2017

Assets		Liabilities and Equity	
Cash	\$1,000,000	Accounts payable	\$250,000
Accounts receivable	\$3,000,000	Long-term debt	\$12,000,000
Inventory	\$200,000	Equity	\$5,950,000
Land	\$1,000,000	TOTAL	\$18,200,000
Buildings	\$10,000,000		
Equipment	\$3,000,000		
TOTAL	\$18,200,000		

over a period of time. Traditionally, revenue appears on the right and expenses on the left. The income statement and balance sheet together comprise the *financial statement*. Hospitals prepare financial statements monthly and generally report results to a board or other oversight body on a monthly, quarterly, and annual basis.

The balance sheet and income statement are fed by data maintained in the hospital's general ledger. The **general ledger** is a record of each transaction of the hospital. Balances on the general ledger are referred to as *trial* or *unaudited balances*, as corrections and changes may be made through an audit process. Reports generated from the general ledger provide significant detail about the institution's activities and finances. A monthly report comparing the actual expenses and activities to the budget for the same period provides pharmacy managers and administrators with information to understand the financial status of the department. These monthly activity reports or responsibility summaries are a key to understanding the financial performance of the pharmacy. **Table 13-2** is an example of a monthly operations report.

FINANCIAL PLANNING

The annual budget is an important part of the pharmacy manager's financial responsibility. A **budget** is a plan for future expenses and revenue, typically over a 12-month period. A budget does not represent the actual amount of money available to be spent. The pharmacy budget is a thoughtful forecast of future expenses and revenue and a benchmark for measuring financial performance.

The Budget Process

Each year the institution develops an annual plan. The institution's CEO, CFO, and Board of Trustees develop goals for services, activity levels, expenditures, and revenues. This is typically done 6–9 months before the fiscal year begins. Forecasts are developed for admissions, service activity, growth, expansion, and other program changes. The director of pharmacy receives these forecasts and begins the process of developing the pharmacy budget. Each institution's budget process varies slightly. However, the CFO provides a budget manual or other instructions, including a calendar for budgeting and an outline of the required approvals and reviews. Instructions may also specify the projections for forecasting inflation and other price increases to be used in budget development. As discussed earlier in the chapter, parts of the budget represent fixed costs that will not vary with activity while others are variable costs, requiring the manager to carefully review forecasts for admissions, patient days, and other volume indicators.

TABLE 13-2.

Example Monthly Operating Statement—Inpatient Pharmacy

Community Hospital Pharmacy

Current Month Actual	Current Month Budget	Difference	Revenue
\$8,485,476	\$8,315,766	\$169,710	Inpatient pharmacy services
\$1,385,651	\$1,357,938	\$27,713	Outpatient pharmacy services
\$9,871,126	\$9,673,703	\$197,423	Total patient services revenue
\$(5,653,838)	\$(5,540,761)	\$(113,077)	Contractual adjustments
\$4,217,288	\$4,132,942	\$84,346	Net patient revenue
Personnel Expenses			
\$32,485	\$31,835	\$650	Salary: management and supervision
\$386,939	\$379,200	\$7,739	Salary: pharmacist and technician
\$16,764	\$16,429	\$335	Salary: support staff
\$10,360	\$10,153	\$207	Overtime
\$9,146	\$8,963	\$183	Shift differential
\$262	\$257	\$5	On call
\$114,935	\$112,636	\$2,299	Employee benefits
\$570,891	\$559,473	\$11,418	Total personnel expense
Non-Personnel Expenses			
\$2,042,204	\$2,001,360	\$40,844	Drugs
\$32,401	\$31,753	\$648	Intravenous supplies
\$13,512	\$13,242	\$270	General medical/surgical supply
\$792	\$776	\$16	Office and general supplies
\$46,910	\$45,972	\$938	Purchased services
\$2,136,346	\$2,093,619	\$42,727	Total non-personnel services
\$2,707,237	\$2,653,092	\$54,145	Total operating expenses
\$1,526,967	\$1,496,428	\$30,539	NET EXCESS

Capital Budget

The budget cycle typically begins with the development of a capital budget. The **capital budget** is usually comprised of items that cost more than a fixed threshold (e.g., an expense >\$5,000) and a useful life greater than 5 years. These thresholds are set by the institution’s Board. Capital expense budgets are generally set several years in advance because many capital expenses can be forecast. The need to replace equipment, renovate or build facilities, or to incur expenses for a new program lends themselves to forward planning.

Capital budget needs are typically larger than the institution can afford, so some prioritization of need may be undertaken, normally a focused review of the expense: Is it required by a new regulation or standard? Is the current equipment broken or nonfunctioning? Is the equipment necessary to support a new patient care program? A review of the **return on investment (ROI)** is also generally used to prioritize or determine the wisdom of making capital purchases. ROI is a structured calculation of the operating cost and revenue

changes that the institution will incur with the new capital expense: Will fewer employees be needed due to increased productivity? Will additional patient volume be available due to increased capacity? Will more revenue be collected? ROI answers the question: “How quickly will it take to earn back the investment made on a capital purchase?” ROI calculations are generally stated in terms of the number of months or years that a capital purchase takes to pay back its purchase cost. Shorter payback periods are generally more favorable, and capital expenses that do not result in payback of their costs may not be easily approved and budgeted, unless they are required to meet a legal or accreditation standard.

Operating Budget

The **operating budget** represents a forecast of the daily expenses required to operate the pharmacy. Development of the health-system budget generally takes advantage of the fact that most expenses are similar in size and scope to prior years. In many organizations, the pharmacy director is presented with a preliminary budget based on the activity for the prior fiscal year. Even when this is not done, the pharmacy director should perform a detailed review of the proposed expenses and revenues by comparing them to the pharmacy’s experience over the past 1–2 fiscal years. Further, he or she should test the proposed changes based on institutional and industry trends, news, and other information. The budget review and approval process generally uses this method to ensure continuity and prevent errors.

Volume Budget

The **volume budget** is prepared by the CFO and supplies the number of admissions, patient days, CMI, outpatient visits, emergency department visits, and other activities. The pharmacy director should examine historical relationships between these volume statistics and pharmacy activity to develop a pharmacy volume budget. **Table 13-3** is an abbreviated example of a pharmacy volume budget developed based on the CFO’s base statistics.

Expense Budget

Pharmacy expenses can be divided into three categories: human resources, supplies, and other fixed expenses.

Human Resource Expense

Human resource expense includes the salaries for all professional, technical, and support staff as well as their benefits (e.g., insurance, workers compensation, disability). The benefit cost is typically stated as a percentage of the annual salary. Benefits cost can run as high as 25% to 30% in some markets. The CFO typically provides the benefit percentage for a pharmacy budget calculation in the annual budget instructions. The pharmacy manager takes

KEY POINT . . .

ROI calculations answer the question: “How quickly will it take to earn back the investment made on a capital purchase?”

. . . SO WHAT?

ROI calculations are not just used for capital purchases: they can demonstrate the return on new pharmacist services and clinical programs. Pharmacists are often told that they need to demonstrate their value to administrators, payers, and other professionals; ROI calculations are a way of doing so. In an ROI calculation, the costs of pharmacy investments must be balanced against the benefits accrued from those investments. Pharmacists need to think about ROIs when proposing any major spending in institutions because administrators and other key decision makers will be doing so.

TABLE 13-3.

Pharmacy Volume Budget

LOCATION	JUL	AUG	SEP	Monthly Average
Inpatient Pharmacy	369,392	369,392	357,476	365,420
Inpatient Pharmacy Total	369,392	369,392	357,476	365,420
<i>Orders/Day</i>	<i>11,915.87</i>	<i>11,915.87</i>	<i>11,915.87</i>	<i>11,915.87</i>
Outpatient Pharmacy #1	16,557	15,869	16,180	16,202
Outpatient Pharmacy #2	9,617	9,885	9,916	9,806
Outpatient Pharmacies Total	26,174	25,755	26,096	26,008
<i>Rx/Day</i>	<i>1,106</i>	<i>1,088</i>	<i>1,140</i>	<i>1,111.32</i>
Home Infusion Pharmacy	11,935	11,935	11,550	11,807
<i>Rx/Day</i>	<i>385.00</i>	<i>385.00</i>	<i>385.00</i>	<i>385.00</i>
GRAND TOTAL:	407,501	407,082	395,122	403,235

the number of approved positions in each job category (e.g., pharmacist, pharmacy technician, secretary) and multiplies them by the number of paid hours for the fiscal year and the hourly rate for the year to arrive at the salary cost. Benefits are added as a percent of the final salary figure. A spreadsheet detailing the calculation for each incumbent employee and with vacant positions listed ensures a correct calculation. Projected raises and salary increases for the coming budget year should be included in this calculation. New positions added to the pharmacy service are typically added to this calculation during the budget review and approval process as they are approved.

Supply Expense

The vast majority of pharmacy supply expense is for drugs, and the size and scope of drug expense have substantial impact on the hospital's overall budget. A thoughtful, well-supported supply budget for drugs is crucial for the pharmacy department's success. Forecasting drug and other supply expense requires knowledge of four factors: (1) level of price inflation, (2) amount of drug utilization, (3) drug mix (i.e., what drugs are used), and (4) a blend of utilization and mix representing expensive, innovative medications. The authors of a continuing series of articles examining trends in hospital drug cost recommend that the pharmacy director and his management team follow a nine-step process to ensure success in forecasting drug expense⁴:

- **Step 1** — Collect data. Historical purchase data can be gathered from wholesaler data systems, and utilization data can be pulled from hospital and pharmacy infor-

KEY POINT . . .

Cost of employee benefits can run as high as 25% to 30% of an employee's salary.

. . . SO WHAT?

Pharmacists often overlook the costs of employee benefits when thinking about personnel costs. When pharmacists negotiate employment contracts with their employers, they need to realize that benefits are a major part of the job offer. When they calculate ROI for new programs, benefits should be added to any salary totals.

mation systems. Group purchasing organizations (GPOs) provide reports on anticipated contract price changes and an annual forecast that serves as a resource for predictions of new drug approvals, adoption of recently approved drugs, generic drug introductions, and overall trends.

- **Step 2** — Review financial history. Evaluate the pharmacy's performance against budget for the most recent full fiscal year and for the current fiscal year (annualizing current fiscal year-to-date data). Compare actual fiscal year data to identify inflationary trends by drug and, when possible, by disease, diagnosis, or clinical service. Identify areas of exceptional variance for more detailed assessment. Review the performance of current pharmacy cost containment efforts.
- **Step 3** — Build a high-priority drug budget. A relatively small number of drugs (<100 products out of the 3,500+ purchased by a typical hospital pharmacy) represent 80% to 90% of total purchases and utilization in most hospitals. Create a drug product-specific budget for these drugs based on historical utilization and project changes in volume of use.
- **Step 4** — Build a new-product budget. Consider new drugs expected to be approved during the period covered by the budget. Work with prescribers and the P&T committee to identify which new drugs will be added to the formulary, how they will be used, and how often.
- **Step 5** — Build a non-formulary drug budget. Budget commonly used non-formulary products separately for financial monitoring purposes.
- **Step 6** — Build a low-priority drug budget. The low-priority drug budget represents a small portion of the total drug budget and can be safely budgeted as a lump sum. This component of the budget should be predicted as a variable cost based on the consideration of any anticipated change in overall patient volume. Other medical supplies and general supplies can also be forecast using this method.
- **Step 7** — Establish a drug cost containment plan. Include consideration of drug-use-evaluation results indicating inappropriate prescribing, drug classes with multiple competing products, and reports of successful cost-containment efforts published by other institutions. For each cost-containment target identified, produce a targeted forecast that includes the scope of the plan, what the intervention will entail (e.g., guideline implementation, formulary change), the timing of intervention implementation, and an estimate of the costs for a fully successful plan.
- **Step 8** — Finalize and present the total drug budget. The total drug budget is the sum of expected expenditures on the high priority list, new products, non-formulary agents, and low-priority products minus the total cost impact expected from the cost-containment plan. In many cases, the initial estimate of expenditures may be higher than hospital leadership is able to support. Using this budgeting model, requests for cuts can be met in a variety of ways.
- **Step 9** — Be vigilant. Budgets established using the eight steps above provide a level of detail and a robust basis for comparison with actual performance and variance reporting.

Other Fixed Expense

Other non-supply expense is generally fixed and varies only in response to inflation and price changes. Non-supply expense consists of a full range of expenditures including salaries, benefits, and overhead.

Revenue Budget

The development of a revenue budget remains an important component of the pharmacy budget, even though few payers actually pay full charge for pharmacy items and services. Pharmacy charges offer an opportunity to track the operations of the pharmacy and serve as a proxy for net revenue after discounts and allowances.

Pharmacy revenue can be predicted from workload volume and from supply expense. Because a detailed volume budget has been developed, the charges associated with this work volume can be forecast. However, since most pharmacy charges are derived from the cost of service, including drug cost, it is important to account for the influence of changes in the mix of drugs used and the influence of increased drug supply cost. Further, the CFO's revenue targets may be set as an overall pharmacy department gross revenue figure. The pharmacy manager must develop a detailed plan that meets the CFO's target using the expense budget.

Budgeting for a New Program

New pharmacy programs that add operating expense should be considered carefully. New drug and supply expense, additional personnel, new equipment, software, and other expenses merit careful consideration. The budget for a new pharmacy program is a smaller version of the budget process described above. Rather than including these new expenses "buried" in the entire budget, a spreadsheet identifying the costs by budget category should be prepared. A narrative supporting the new program including objectives, program description, advantages, resources required, and a bottom line should be developed. Many organizations also consider indirect costs for new programs, although they are generally not a significant part of the annual budget process for the pharmacy.

Budget Negotiation, Review, and Approval

After all departments develop their budgets, they are returned to the CFO or budget office for a "roll-up" where the individual department budgets are aggregated, and a first version of a working budget for the health-system is created. Because the budget development process takes place at the department level, the resulting budget draft generally needs substantial work. The CFO and Finance team work to balance the budget, to identify errors and problematic assumptions, and to develop a workable budget plan.

The institution's administration, led by the CEO and CFO, set priorities for funding and ask departments to change, cut, reduce, or otherwise modify their initial budget proposals. Some requests for change or new programs may be deferred to future years or denied outright. Budget development is both a rational and a political process; negotiations revolve around the organization's highest priorities and the quality of preparation and presentation made by the respective department leaders.

Pharmacy budgets developed as described above are evaluated against prior fiscal year experience to ensure that they are realistic and reasonable. The integrity of the development process and the level of support for key assumptions such as pharmacy volumes, drug price increases, and new drug adoption are also a factor in considering how the pharmacy budget is considered and accepted. The track record of the pharmacy and the pharmacy director in meeting prior budgets often has significant influence on the outcome of the current budget review. A thoughtful, well-developed budget supported by data has the greatest chance of success and provides the health system with the best forecast of the future.

Monitoring the Budget

During the fiscal year, the hospital finance team collects information and manages the hospital's expenses and revenues to meet the objectives set in the budget process. The

institution's financial management data systems collect volume, expense, and revenue data in real time. Monthly activity reports are provided to pharmacy managers. These reports provide a summary of expenses in each of the areas where the pharmacy spends and receives money, and compare it to the target set for the month and for the fiscal year to date. The pharmacy director should review the reports and take action to address financial issues in the pharmacy to ensure that the pharmacy department meets targets set during the budget process. Alternatively, if the report shows changes that were not anticipated in the budget process (e.g., a new high-cost drug is introduced earlier than anticipated), and the pharmacy will not meet the budget target, regular review will ensure that action is taken to resolve the problem, or appropriate action is taken to alter the budget to reflect the new reality.

VARIANCE ANALYSIS

Variance analysis can be illustrated using the pharmacy department monthly operating statement shown in Table 13-2. A **variance** is a difference between the budgeted amount and the actual amount spent for a budget period, typically a month. Variances are generally evaluated monthly: examining monthly changes and variance from the start of the fiscal year to date. Variances can be described as *positive* (expenses lower than forecast; revenues higher than forecast) or *negative* (expenses higher than forecast; revenue lower than forecast). A positive variance is one that allows the hospital to retain more cash, while a negative variance causes the hospital to have less cash than the budget forecast. Variances can be absolute—the total actual spent amount is higher irrespective of volume—or adjusted by volume; the variance in cost cannot be explained solely by changes in activity volume.

Some variation in expense and revenue is expected—human resource cost should hover within 2% of that forecast, while drug expenses might have a 5% to 10% acceptable variance. It is the unexpected that should catch the pharmacy manager's attention, considering both the magnitude of variance and the ability to influence it. The absolute variation in expense may also be considered cause for review. Each hospital sets the acceptable limits for budget variance; typically a threshold is set by the CEO or CFO.

Determining the Cause of Variance

Operating statements like that in Table 13-2 are designed to identify the nature of expense variance. To determine the sources of variance, the pharmacy manager must look at each category of expense that meets the threshold for investigation. A human resource expense might have a positive variance if a job opening exists for a position resulting in salary savings. A negative variance in human resource expense might result from additional overtime expenses required to meet a specific patient care need. Supply expense variance might be positive if a high-cost drug was released onto the market later than expected. On the other hand, supply expense might show a negative variance if an outbreak of an infectious disease caused a higher than anticipated use of a costly antibiotic, if a shortage of medication caused the pharmacy to switch to a more costly drug, or if drug prices rose faster than forecast. Both human resource and supply cost might be higher than

KEY POINT...

Some variation in expense and revenue is expected. It is the unexpected that should catch the pharmacy manager's attention.

...SO WHAT?

Basic knowledge of computer spreadsheets and their graphing capabilities are an essential skill for pharmacists. These programs allow data to be manipulated in ways allowing pharmacists to pick up data patterns that are otherwise not visible. They help differentiate the unexpected from the expected.

anticipated if the hospital census was higher than budgeted, resulting in negative variances for both categories.

Pharmacy leaders are expected to have a continuing, current understanding of the nature and source of expense variance. Their understanding should include both the business and clinical therapeutics understanding for which they are trained. The regular discipline of monthly analysis provides an opportunity to understand and to take action to ensure that the hospital's funds are expended wisely.

INTEGRATING COST AND REVENUE ANALYSIS

As reimbursement for healthcare services has become more competitive, pharmacy managers have had to make hard choices based upon profitability of services. Cost alone is insufficient for deciding the most appropriate course of action in managing drug use and pharmacy costs. The payment system for patient care services and DRGs often creates the need to ask a more fundamental question: "Does the hospital make or lose money on treating this type of case?"

Most case rates are determined based on the current standard practice or on some other current norm. However, introduction of a costly new drug or treatment onto the market or when treatment protocols or standards change, the cost of medications may exceed the amount paid and the profitability of the case can change. Therefore, decisions about whether to add drugs to the formulary, new practice guidelines, and other choices made by P&T committees and pharmacists should consider not only the cost and cost-benefit relationships associated with a particular drug therapy, but also the reimbursement received by the hospital. Revenues and costs are time-consuming to track in a health system. However, a thoughtful pharmacy leader must consider the implications of revenue and margin in choosing a course of action. This is a critical skill, particularly when high cost and high impact drugs are considered for use in a hospital.

PRODUCTIVITY MEASUREMENT AND BENCHMARKING

The budgeting process helps hospitals measure productivity. Productivity is defined using the following equation:

$$\text{Productivity} = \text{Output/Input}$$

Because the budget develops indicators of input (supply costs, hours worked, salary costs) and outputs (doses dispensed, patients treated, patients discharged), a baseline for calculating productivity is created. Although productivity measured in this way is a key management indicator, movement to an assessment of the impact of pharmacy services based on patient outcomes has added an additional dimension to the role of workload and productivity measures.

Productivity measures can also be designed using detailed time and motion studies or through the use of benchmarking. **Time and motion studies** consist of a detailed analysis of the time it takes to complete various tasks. These studies determine the resources necessary to complete tasks, and the results are used to set goals for improvement or change. Benchmarking uses data collected from some comparator (e.g., peer institutions, past performance) to set standards for productivity.

External benchmarking is a process of measuring costs, services, and practices against the organization's peers or against industry leaders. The goal of external benchmarking is to find and implement the best practices of peer organizations. External benchmarking presents a significant challenge. The idea behind external benchmarking is attractive, but

because there is limited information about peer institutions, incorrect or inappropriate comparisons may be made. The real cause of differences indicated by key external benchmarking indicators may result from factors outside the scope of the data collected and compared. As examples, differences in hospital information systems, the size, layout, and logistics support in the hospital facility, or even the allocation of medication delivery tasks between pharmacy and nursing may have substantial impact on the reported productivity indicators across two hospitals. External benchmarking does offer an opportunity to identify variation in performance across a group of industry peers and to target opportunities for investigation. But excessively rigid or overly casual use of external cost and labor benchmarks can create significant problems by identifying false improvement opportunities or setting performance goals that are unreachable or are inappropriately low.

In contrast, **internal benchmarking** is the process of measuring costs, services, and work volumes and activities against the organization's prior performance. The goal of internal benchmarking is to refine and improve the organization's performance incrementally over time. Internal benchmarking does not assist in identifying best practices. It assesses the impact of changes in systems, practices, and procedures in a standard set of measures. Internal benchmarking against prior department and health-system performance offers a different analysis of improvement opportunities and assesses them in a more data-rich fashion. A full understanding of quality and safety issues, combined with a broad assessment of changes in case mix, programs, and other variables make internal benchmarking a more robust methodology. Because productivity and operational benchmarking lack a quality of care and outcome dimension, they are being displaced by *dashboard* and *scorecard* methodologies that incorporate indicators of quality and outcome into efficiency and effectiveness review. Because internal benchmarking of data is a high level assessment, typically department-wide, it may not be sensitive enough to detect small but important internal improvements in pharmacy processes. Further, cross-functional and interdepartmental productivity improvements (e.g., implementation of computerized physician order entry) require collaboration and separate analysis.

Budgeting, time and motion, and benchmarking all seek to develop a ratio of input to output expressed as monetary cost/unit of output or hours worked/unit of output. **Table 13-4** lists examples of productivity measures used in evaluating pharmacy services and medication therapy. Some productivity measures do not measure the full range of pharmacy service activities. For instance, productivity measures based on the number of doses charged or dispensed by a pharmacy ignore the application of pharmacist's knowledge and skills complexity in resolving clinical care issues.

KEY POINT...

The payment system for patient care services and DRGs requires pharmacists to ask a fundamental question: "Does the hospital make or lose money on treating this type of patient case?"

...SO WHAT?

The answer to this question can influence strategies for serving patients within institutions. Health systems might target patients with conditions associated with profitable DRGs, seeking to attract these patients with innovative services or other offerings. Alternatively, interventions could be developed to reduce the costs of treating patients associated with unprofitable DRGs.

For instance, patients could be tracked as they move throughout the healthcare system, identifying inefficiencies and unnecessary costs.

TABLE 13-4.

Example Pharmacy Productivity Ratios

Labor Productivity Ratios

- Hours worked per adjusted patient day
- Hours worked per adjusted discharge
- Hours worked per 100 orders processed
- Hours paid per adjusted patient day
- Hours paid per adjusted discharge
- Hours paid per 100 orders processed

Cost-Base Productivity Ratios

- Drug cost per 100 orders processed
- Supply cost per 100 orders processed
- Labor cost per 100 orders processed
- Total cost per 100 orders processed
- Drug cost per adjusted patient day
- Supply cost per adjusted patient day
- Labor cost per adjusted patient day
- Total cost per adjusted patient day
- Drug cost per adjusted discharge
- Supply cost per adjusted discharge
- Labor cost per adjusted discharge
- Total cost per adjusted discharge



SUMMARY

Pharmacists and pharmacy leaders' thoughtful financial management is critical to the success of the organization's pharmaceutical care plan. A working knowledge of financial management supports the effective delivery of high-quality pharmacy services, and supports optimal achievement of the patient care mission of the pharmacy and the hospital. Pharmacy leaders can balance costs, benefits, and patient care outcomes in delivering pharmaceutical care using an organized data-based budget, monitoring variance, and assessing as well as managing costs and revenues.

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CHAPTER REVIEW QUESTIONS

1. What is a direct expense?

- a. Monies received by the hospital based on pharmacy services.
- b. Expenses incurred by the pharmacy to deliver services and products.
- c. Expenses covered by third-party plan payments such as a PBM.
- d. Expenses paid by the hospital to support the pharmacy such as hospital administration salaries.

Answer: b. Direct expenses result directly from the delivery care to patients. Answer a describes a source of revenue. For answer c, direct expenses can be part of expenses covered by third party plans, but not all. Answer d is a type of indirect (or overhead) expense.

2. Flaws of external benchmarking include which of the following?

- a. The real cause of differences may result from factors outside the scope of the data collected and compared.
- b. Because there is limited information about peer institutions, incorrect or inappropriate comparisons may be made.
- c. External benchmarks can identify false improvement opportunities or set inappropriate performance goals.
- d. a and c
- e. All of the above

Answer: e. All of the above. External benchmarking consists of comparing one's organization with an outside organization. Answers a, b, and c are all flaws of external benchmarking because comparing oneself with others is problematic if the wrong data are collected, the collected data are not accurate, and attempts to mimic others may not be the right strategy for your institution.

3. Which of the following statements is NOT true of a variable direct expense in hospital pharmacies?

- a. They are costs that rise and fall in the short term with the level of activity.
- b. Purchase costs for drugs are an example of a variable direct expense.
- c. The number of orders processed and prescriptions dispensed affect work volume and may drive variable expenses.
- d. Most hospitals do not consider pharmacy supply cost to be variable based on volume.
- e. Pharmacy manpower is generally budgeted as a variable expense.

Answer: d. Pharmacy supplies, including drugs, vary based upon the number of patients in the hospital because they are directly associated with the treatments of these patients.

Answers a, b, c, and e all describe variable direct expenses of a hospital pharmacy.

4. Hospitals generally use return on investment (ROI) as a method to determine whether to make a purchase or start a new service. Which of the following is true regarding ROI?

- a. ROI is a structured return-on-investment calculation that looks at the amount of time it takes to “break even.”
- b. ROI must be considered in light of other items (e.g., regulatory requirements) and may not be the sole determinant of a decision.
- c. ROI may not have a fixed threshold, but may be used to set spending priorities when health systems have insufficient capital to pursue all proposed projects.
- d. All of the above
- e. None of the above

Answer: d. All of the above.

5. The case rate payment method is designed to do which of the following?

- a. Encourage hospitals to provide care economically.
- b. Limit cost overruns in pharmacy spending.
- c. Allow the hospital to be the beneficiary of improved savings and efficiencies.
- d. Encourage the use of costly medications when they limit the length of a hospital stay.
- e. a and c
- f. b and d

Answer: e. Answer a is correct because case rate payments cap the amount of money received for treating patients, and c is correct because case rate payments also allow hospitals to keep any money left over. Answer b is incorrect because higher pharmacy spending may result in lower treatment costs due to the relative cost effectiveness of drugs compared to other treatment alternatives. Answer d is incorrect because use of costly medications is unprofitable if lower cost alternatives are available.

6. Indirect expenses are payments for services that support the pharmacy but are not directly paid by the pharmacy. Which of the following are examples of indirect expenses?

- a. Hospital administration costs.
- b. Non-drug supply items (e.g., IV bags, syringes, packaging materials used in pharmacy preparations).
- c. Information Technology (IT) (e.g., the hospital's electronic medical record).
- d. Licenses, taxes and fees related to regulatory compliance and accreditation.
- e. a and c

Answer: e. Answers b and d are not true.

7. Forecasting drug expense is a combination of four factors. Which of the following correctly identifies these factors?

- a. Formulary status, medication error review, new drug factors, and generic substitution.
- b. Price inflation, drug utilization, drug mix, and a blend of utilization and mix of high-cost medications.
- c. High-hazard medications, MTM requirements, clinic and hospital visit volume, and a mix of high-cost medications.
- d. Clinical service factor, medication utilization review, price inflation, and drug utilization.

Answer: b. Price inflation, drug utilization, drug mix, and a blend of utilization and mix of high-cost medications are all functions of overall drug expenses. Drug expenses are determined by price multiplied by the amount used. Price inflation refers to price increases; drug utilization, drug mix, and the blend of utilization and drug mix refer to the amount used.

8. The operating budget is a forecast of the daily expenses required to operate the pharmacy. Which of the following is a correct statement regarding the operating budget?

- a. The operating budget is only a suggestion; it can be treated casually when considering the pharmacy operation.
- b. The pharmacy operating budget may include high-cost equipment items that have an extended useful life, typically beyond 5 years.
- c. The pharmacy director is typically presented with a preliminary budget based on the prior year's operating expense.
- d. The pharmacy operating budget does not include drugs. They are included in a special supply budget.

Answer: c. The operating budget typically starts with what was used in the prior (current) year with adjustments based on a forecast of how the coming year will differ from the current year. Considerations about the rate of drug price inflation, increases in pharmacist compensation, new programs, impact of cost savings initiatives, and so on will determine the new budget.

9. What is an asset?

- a. Anything of positive value about the operations of the health system including reputation, employee staff, and key programs such as oncology or transplant.
- b. A statement of an amount of money owed to the health system by a payer or patient.
- c. Real, intangible, and financial items owned by the health system including buildings, equipment and inventory, and cash and accounts receivable.
- d. Unpaid bills the hospital owes to suppliers, loans and bonds issued.

Answer: c. Assets are things that either can be touched (buildings, inventory) or not (promises to pay, electronic totals of money in the bank).

10. The operating budget represents a forecast of the expenses required to operate the pharmacy. Which of the following are true statements?

- a. The volume budget supplies the number of admissions, patient days, CMI, outpatient visits, emergency department visits, and other activities.
- b. Parts of the budget represent fixed costs that will not vary with activity for admissions, patient days, and other volume indicators.

- c. The capital budget is usually comprised of items that cost more than a fixed threshold and a long useful life.
- d. The development of a revenue budget is important, even though few payers actually pay full charge for pharmacy items and services.
- e. a and c
- f. All of the above

Answer: f. All of the above are correct.

CHAPTER DISCUSSION QUESTIONS

1. What advantage would a pharmacist gain by understanding general costs and revenues associated with his or her work?
2. How might the value of clinical and professional pharmacy services be determined in an ROI or ROE evaluation of a new program or service?
3. What types of expense and revenue variance are within the control of pharmacy? Which are not? How would strategies to address variance differ for each category?
4. Which is a preferred method: external benchmarking of a pharmacy or internal benchmarking? Why? What are the advantages of the method that you selected?
5. How might clinical specialist pharmacists contribute to the budgeting process?

Providing Sustainable Pharmacy Services in Ambulatory Care

David A. Holdford

LEARNING OBJECTIVES

After completing this chapter, readers should be able to:

1. Discuss the need to make ambulatory pharmacy services sustainable.
2. Describe business models and their components.
3. Explain the foundations of sustainable business models.
4. Identify the components of a business plan.

KEY TERMS AND DEFINITIONS

- **340B Drug Pricing Program:** The federal program that allows eligible hospitals and other healthcare institutions to purchase outpatient drugs at significantly reduced prices from drug manufacturers. Manufacturers are required to offer 340B discounts to covered institutions if they want their medications covered under state Medicaid programs. In addition to Medicaid patients, qualified institutions can offer 340B eligible medications to uninsured, Medicare, and some privately insured patients.
- **Ambulatory care:** The medical care provided to patients who do not reside in the hospital; also called outpatient care. Pharmacy services in ambulatory care are typically more comprehensive than that seen in retail community pharmacies. Pharmacists work in

healthcare teams responsible for diagnosis, treatment, and rehabilitation.

- **Business case:** The financial argument designed to convince decision makers and other stakeholders to support new or expanded ambulatory services. The justification generally articulates how the additional costs of pharmacy services will generate a positive return on investment (ROI).
- **Business model:** The model that describes how businesses (e.g., hospitals) or business components (e.g., pharmacies) plan on generating resources (e.g., revenue), which allows them to be sustainable over time.
- **Business plan:** A written document that details how a business or business component will try to accomplish its goals. It contains many of the elements of a business model but lays out more detailed steps for implementing the business model.
- **Charge:** The amount a healthcare provider asks to be paid or compensated for doing a job. It differs from compensation (the amount actually paid). This is an important distinction because healthcare providers charge amounts that are often much more than what customers like health insurance companies actually compensate.
- **Compensation:** The payment for doing a job like discharge counseling or medication therapy management services.
- **Cost:** The amount of resources needed to produce goods or services. It consists of inputs like employee salaries, facilities, overhead, materials, and other production costs.

- **Cost neutral:** An initiative that generates revenues equal to the costs of providing it. The ROI on a cost neutral initiative is 1 (see ROI definition).
- **Customer value proposition (CVP):** The description of how a business creates value for customers by solving important problems better than anyone else. It is the case made for its utility to customers.
- **Fee-for-service:** A model of paying for healthcare that rewards providers for unbundled, separate units of service. This model is common in pharmacy where payments (i.e., dispensing fees) are paid for each individual prescription filled rather than for improving the health outcomes associated with those dispensed prescriptions. This model incentivizes the provision of more care without considering its quality.
- **Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS):** The patient satisfaction survey that measures patient perceptions of their hospital stay based on satisfaction with communication with doctors and nurses, staff responsiveness, pain management, communication about medicines, discharge information, cleanliness and quietness of the hospital environment, and overall rating of care.
- **Hospital Inpatient Value-Based Purchasing Program:** The program that makes changes in Medicare compensation to hospitals based on value-based purchasing measures related to four major dimensions of performance: clinical processes, patient outcomes, measures of efficiency, and patient experience.
- **“Incident to” services:** Services, which are submitted to Medicare and provided by non-physician practitioners like pharmacists, under the physician’s National Provider Identifier (NPI) number. They are called “incident to” because they are provided after first being evaluated by the physician or for a service covered by Medicare.
- **Key performance indicators (KPIs):** Measures that organizations use to evaluate their success in achieving specific activities relating to their mission. KPIs are often linked to managers’ compensation and, therefore, drive decisions about what should and should not be done.
- **Needs assessment:** A systematic process to identify gaps between existing conditions and what is desired. The process is used to identify opportunities to improve health-care.
- **Medicare Star Rating Program:** A rating system to assess the performance of Medicare Advantage and prescription drug (Part D) plans. Scores range from one to five stars, with one being the lowest and five being the highest score. Medicare scores how well plans did in several categories, including medication adherence and annual comprehensive medication reviews. These star ratings are linked to payment incentives to insurers.
- **Pay-for-performance (P4P):** A model of paying for healthcare that rewards providers for meeting established performance measures for quality and efficiency. Alternatively, it may penalize providers who are associated with poor outcomes, medical errors, or increased costs.
- **Pharmacist champion:** A pharmacist who is committed to the success of a pharmacy initiative. A champion takes ownership of the initiative and ensures that all tasks and objectives are achieved.
- **Return on investment (ROI):** The ratio of net revenue or other benefit received from an investment on a new service divided by the net costs of that service. A ratio greater than one is considered to be a positive ROI. It is sometimes reported as a percentage (e.g., a ratio of 1.2 equals a 20% ROI).
- **Revenue:** The total amount of income (i.e., money) received by an entity (e.g., pharmacy) from all sources. Revenue might come from compensation from services, sales of merchandise, grants and donations from organizations, or any other source of income.

- **Sustainable services:** Services defined as those that are able to be maintained over a long time. To be sustainable, a pharmacy must cover its costs of providing services in a way that maintains or supports itself over the long term.
- **SWOT analysis:** A common tool used to guide business plans, which systematically analyzes the strengths (S) and weaknesses (W) of the pharmacy or institution in relation to an evaluation of the opportunities (O) and threats (T) in the business environment.
- **Value-based purchasing (VBP) programs:** A general model of paying for healthcare that considers the relative cost paid for the quality of healthcare purchased. An example is the Centers for Medicare & Medicaid Services Hospital Inpatient Value-Based Purchasing Program. In pharmacy, private and public payers of healthcare link VBP compensation to pharmacies for their performance on generic substitution, therapeutic substitution, incentive-based formulary, and value-based insurance design programs.



INTRODUCTION

There is significant interest in hospitals and health systems to treat more inpatients in outpatient settings due to relative advantages of outpatient treatment. Outpatient services are less expensive to deliver—they do not have the costs of staying open 24/7 or the overhead costs associated with running a large healthcare facility. In addition, patients tend to prefer outpatient services. Few patients want to stay overnight in a hospital away from their friends, family, and home comforts.

Similarly, there is significant interest for hospitals to expand pharmacy services in outpatient settings.¹ However, there are financial barriers to providing comprehensive pharmacy services associated with the fact that current **compensation** systems for pharmacists reward the dispensing of medications, not clinical services.

Ambulatory pharmacy in institutional settings need new **business models** to survive and grow.² A business model describes how businesses (e.g., hospitals) or business components (e.g., pharmacies) generate sufficient resources (e.g., revenue) to allow them to be sustainable over time. **Table 14-1** describes the elements that comprise a business model.

Business models for pharmacist services must be financially sustainable. Financial sustainability occurs when the costs of delivering medications and pharmacist services are covered over time by revenue received from fees, compensation, savings, or other sources of financial benefits. Ambulatory pharmacies can be sustainable only if they cover pharmacist salaries (e.g., salary and benefits for pharmacists can average over \$150,000 per year), technician salaries (e.g., salary and benefits for technicians can average over \$40,000 per year), operating expenses, costs of facilities, and other costs. At a minimum, ambulatory pharmacy services should be at least **cost neutral** (i.e., where revenue received equals the costs

KEY POINT . . .

Business models describe how pharmacies make money when serving patients, physicians, nurses, insurance companies, payers, and other customers.

. . . SO WHAT?

Pharmacy services cannot be sustained over time if they do not cover the costs of providing them. Administrators may temporarily support services in their startup phase, but they will pull the plug on any initiative that cannot support itself in the long run.

TABLE 14-1.
Elements of Business Models in Ambulatory Pharmacy

- Business models explain how businesses serve customers in a lasting and self-sustaining manner.
All business models describe three primary things within a business.³
 1. **The customer value proposition (CVP):** A CVP is a description of how a business creates value for customers—by solving important problems better than anyone else. It is the case made for its utility to customers.
 2. **Resources and processes:** Creating value requires resources. Resources refer to the people, technology, merchandise, facilities, location, and other things needed to deliver the value proposition to the customer. Processes describe the ways that operations and management use resources to deliver value in a sustainable way. These processes might include tasks like inventory control, purchasing, budgeting, information management, service design, and service management.
 3. **Profit formula:** It defines how sufficient revenues are generated by the business to cover the costs of providing the CVP over time.
- Business models attempt to describe how these three interdependent components result in a long-lasting business that serves customers.
- Ambulatory pharmacists have traditionally worked under fee-for-service business models in which providers generate revenue by charging a fee in compensation for work done. In ambulatory pharmacy, the majority of those fees are charged for selling medications. Fees are also charged for clinical services like anticoagulation monitoring and disease management programs, but clinical services rarely produce much of the overall revenue of an outpatient department.
- **Fee-for-service business models offer a combination of two primary customer value propositions: economic and functional.⁴**

The *economic value proposition* argues that the marginal benefits (i.e., utility) pharmacists offer to patients is greater than the costs of providing them. Stated differently, they offer greater value than they cost. Economic value propositions are usually combined with functional value propositions.

A *functional value proposition* centers on offering convenience to patients. Services and medications are provided quickly, requiring little effort on the part of patients. Examples of functional value propositions are nearby locations, fast service, liberal hours of operation, home-delivery, 24-hour access to pharmacists via telephone or online services, and other conveniences.

expended), although sustainability usually requires revenue to exceed costs to generate profits that can be reinvested into the pharmacy.

Currently, the primary **fee-for-service** payment models available to ambulatory care pharmacists pay for only the cost of the medicine plus a small dispensing fee. This compensation merely covers minimum levels of service—not complex care. To fund and sustain higher levels of clinical services, ambulatory care pharmacists need to develop new streams of revenue.

FOUNDATIONS OF SUSTAINABLE BUSINESS MODELS

Business sustainability requires four things: effective leadership, staffing, information technology and automation, and the ability to make a successful **business case**.^{2,5} Gaps in any of these needs can cause the failure of pharmacy **ambulatory care** services.

Effective Leadership

Providing sustainable pharmacy services in institutional pharmacy settings requires effective leadership. Leaders must develop and articulate a clear vision about the need for

ambulatory services and motivate staff to follow that vision. Clearly setting the pharmacy's direction and priorities ensures that they become a priority throughout the pharmacy. The leader's role in communicating a coherent vision to subordinates is crucial. A shared vision of service can excite people and motivate them to function at the top of their license (i.e., practicing to the full extent of one's education and training). Leaders must be able to stress the importance of ambulatory services in both words and actions. The leader's commitment to ambulatory services must be shared by pharmacy staff involved in providing those services.

Leaders are also essential for nurturing relationships with stakeholders within and outside of the pharmacy. Within the healthcare institution, stakeholders include administrators, physicians, and nurses. Stakeholders outside of the institution include suppliers, employer groups, insurers, governmental regulators, and local community pharmacies.

Within the institution, leaders must compete for resources with other priorities and departments. They must advocate for the value of ambulatory care services and make a case for how pharmacy services make business sense. Pharmacy leaders need to obtain commitment from internal stakeholders to provide adequate staff resources to develop or expand ambulatory services.

Outside of the institution, effective leaders cultivate relationships with payers, insurers, regulators, and local pharmacies that might support pharmacy initiatives. Payers and insurers must support the pharmacy by agreeing to compensate clinical services as well as providing contracts for the filling of their patients' prescriptions. Regulators need to remove potential regulatory barriers to innovative services. Relationships with local pharmacies can be cultivated to make them partners, rather than competitors with ambulatory services.

A crucial leader in developing or expanding ambulatory services is the pharmacist champion. The **pharmacist champion** is the person who takes responsibility for the success of pharmacy initiatives. The champion may possess a formal managerial title or simply be an informal leader who volunteers to take ownership of the initiative. Pharmacist champions ensure that all tasks and plans are completed. They troubleshoot team conflicts, deal with billing and insurance issues, address staffing deficiencies, and complete all of the details needed to get ambulatory services up and running that include regulatory compliance with state and federal laws.

Staffing

Sustainable pharmacy business models need enough trained pharmacists, support staff, and funding to effectively serve patients. This means identifying the staffing and training needed to provide high levels of clinical and administrative care. Pharmacists who have completed residency programs, certificate programs, or other specialized experiences may not need much additional training, but other pharmacists might require further training. Training may also be required of pharmacy technicians and clerical staff who support pharmacist activities. Support staff can help in scheduling patients, submitting bills, and calling patients who fail to keep their appointments. In addition, support staff can help patients overcome insurance barriers and secure essential medications.

When starting a new service, it might be tempting for pharmacists to perform their own clerical work with hopes of delegating these tasks later as the workload increases. Another option is to develop service processes that are scalable, meaning that they can be easily expanded as demand increases. Pharmacists who do not plan for scalability often regret it as programs grow.

Pharmacy staffing needs can be better managed by coordinating with physicians, nurses, and other professionals in the ambulatory clinic. Services can run smoother by adopting similar processes for referrals, scheduling, ordering tests, and so on. Staffing capabilities can also be expanded by offering new training opportunities like ambulatory care residencies, internships, and fellowships. These educational options can help students to learn by doing and identify future hires for the ambulatory department. Partnering with a local college of pharmacy to co-fund faculty members or to provide advanced pharmacy practice experiences for students are other ways of managing staffing costs. Partnerships with local community pharmacies, wholesalers, and independent consultants can also be used to co-fund staff or provide other forms of support for pharmacy staff.

Information Technology and Automation

Ambulatory pharmacy services cannot be sustained without the right information technology support. Technology drives all aspects of patient care delivery and management and is needed to provide safe, accurate, and efficient services.

Information technology is essential for prescription adjudication, medication preparation, dispensing, and clinical monitoring. Bar-code technology helps in tracking orders and making certain that patients receive the medications prescribed for them. Safety and productivity is enhanced when automation and information technology interface between the inpatient and outpatient pharmacy systems and with other non-pharmacy systems (in many cases, the electronic medical chart and pharmacy system are the same parent program [i.e., EPIC]) like the electronic medical chart and e-prescribing systems. When all of the systems can “talk” to each other, care can be provided across the full continuum of care.

Systems also need to connect the electronic pharmacy and medical records to mobile devices like tablet applications for counseling, monitoring devices with Bluetooth capabilities, documentation systems that permit the sharing of records, and alert and reminder systems.² Well-designed and supported information technology and automated systems are essential for efficient and effective care coordination.

Billing technology systems are particularly important when providing new ambulatory services. They need to quantify what services pharmacists provide and for how long. That information then needs to match the workload to internal provider numbers and billing codes to ensure that pharmacist work is compensated. The technology needs to generate periodic reports on the number of new patient visits, follow-up patient visits, patient diagnoses, and revenue generated within the pharmacy. Reports can be given to managers and agencies that publicly report quality performance.

Ability to Make a Business Case

The ability to make a successful business case is the most important factor needed to provide sustainable ambulatory care pharmacist services.⁵ A *business case* is a financial argument designed to convince decision makers and other stakeholders to support new or expanded ambulatory services.⁶ The justification in a business case generally articulates how the additional costs of pharmacy services will generate a positive **return on investment (ROI)**, meaning that the costs of investing in the services are more than offset by the financial benefits received. Most pharmacists have limited training and experience in justifying their worth. Nevertheless, they need to learn to do so if they want to be supported by internal and external stakeholders.

A business case can be made by demonstrating that net revenue from a new initiative will exceed the cost to provide it. Therefore, a business case must argue that the cost of ambulatory pharmacy services will be offset by an increase in overall healthcare revenues, a reduction in overall healthcare costs, or both.

Before continuing, it is useful to define some terminology relating to costs, compensation, and revenue because they can be confusing for nonbusiness professionals. Providing ambulatory pharmacy services create costs. *Costs* such as employees' salaries, facilities, overhead, materials, and other production expenses are resources expended when producing services and dispensing medications. To cover these costs, pharmacists need to be compensated. *Compensation* is the financial payment received for providing ambulatory services like discharge counseling or medication therapy management. Compensation is a form of revenue. *Revenue* is total amount of income (i.e., money) received by the pharmacy from all sources. Revenue might come from compensation from services, sales of merchandise, grants and donations received from organizations to support pharmacy services, or any other source of income.

Generating Compensation

CAPTURING ADDITIONAL DISPENSING

REVENUE: Every patient discharged from an inpatient setting takes potential revenue with them if they go to the pharmacies outside of the discharging institution.

Institutional pharmacies can generate additional revenue simply by capturing dispensing revenue that might go to others outside of the healthcare system. This includes discharged patients and hospital employees and dependents who currently receive their medications from local community pharmacies. Revenue can also be generated by serving additional groups who may be receiving medications outside of the ambulatory care clinic. Additional groups include:

- Patients who visit the emergency department
- Individuals receiving same-day surgeries
- People served by the health-system's outpatient clinics
- Prisoners coming from local jails to be seen at the health system's outpatient clinics
- Hospice patients
- Patients discharged from hospitals
- Patients served by eligible state and local government programs
- Specialty pharmacy patients receiving high-cost medications for cancer, human immunodeficiency virus (HIV), and other conditions

Ambulatory pharmacies have a competitive advantage over community pharmacies when serving patients covered by the 340B Pricing Program. The **340B Drug Pricing Program** is a federal initiative that allows eligible hospitals and other healthcare institutions to purchase outpatient drugs at significantly reduced prices from drug manufacturers.⁷ Manufacturers are required to offer 340B discounts to covered institutions if they

KEY POINT . . .

A business case can be made for pharmacists if they show that the cost of ambulatory pharmacy services will be offset by an increase in overall healthcare revenues, a reduction in overall healthcare costs, or both.

. . . SO WHAT?

Healthcare is a business, which can only survive by generating enough money and other resources to cover its needs. Generating additional compensation is one way to justify the existence of pharmacy services.

Another way is to show how pharmacists can influence spending on medications and reduce penalties for not achieving performance goals set by payers. Pharmacists need to understand and influence all available avenues for revenue generation and cost reduction.

want their medications covered under state Medicaid programs. Eligible institutions include those providing significant amounts of charity care and qualifying facilities providing critical care to underserved populations like rural or HIV patients. Savings to providers have been reported to range from 25% to 50%.⁷

The 340B pricing rules can be very complex, but a basic understanding is needed when providing ambulatory services. Patients served by the pharmacy can be divided into 340B covered and non-covered individuals. Billing and inventory management must handle each group of patients separately. This is critical because charging patients 340B prices when they are not covered is prohibited by law.

An institution's outpatient pharmacy can provide pharmacy services to 340B-eligible patients, or they can be outsourced to an external community or specialty pharmacy. Outsourcing may appear to be an easy solution to institutions with limited resources. However, outsourcing can be short-sighted because expansion of ambulatory pharmacy services can be financed in part by capturing revenue that goes to other providers.

Compensation for 340B-covered prescriptions is typically more generous than that offered for non-covered prescriptions paid by private insurance. Payers routinely reimburse pharmacies more for the cost of the medicine. In addition, an administrative fee is paid that covers the cost of dispensing and additional professional services like drug utilization review and screenings. These fees average approximately \$9 to \$12 per prescription, which are generous in comparison to fees paid by most insurers.⁸ Compliance with 340B is an excellent example of how leadership, appropriate staffing, automation and information technology, and a solid business case come together to support new initiatives.

BILLING INSURANCE COMPANIES AND PATIENTS DIRECTLY: Compensation for ambulatory pharmacy services other than dispensing (e.g., diabetes management) consists of charging customers for the cost of care. A **charge** is what a healthcare provider asks to be paid for doing a job. Bills for these charges generally go to health insurance companies or directly to patients who are asked to pay out-of-pocket.

The problem for pharmacists with billing insurance companies and patients directly is that many of these bills are not paid. Uninsured patients are often unable or unwilling to pay for non-dispensing services. The same is true for insurance companies. Many insurers can ignore or deny the charges because there is no legal requirement or consensus for doing so. This problem occurs because pharmacists are not formally recognized as healthcare providers in key sections of the Social Security Act (SSA). The SSA determines eligibility for pharmacist services to be funded under healthcare programs such as Medicare Part B.

The omission of pharmacist recognition as providers under the SSA allows insurers, including state Medicaid agencies, to deny compensation for provided services. Major pharmacy associations have been lobbying for years for pharmacists to receive formal recognition as providers, but until they succeed, this oversight will continue to hinder the capacity to provide sustainable pharmacy services.

BILLING PAYERS "INCIDENT TO": Because pharmacists have had limited success in directly billing for their services, they have had to develop workarounds to receive compensation. One such workaround is to bill insurers through the Outpatient Prospective Payment Systems **incident to** physician services. The Hospital Outpatient Prospective Payment System (HOPPS) describes who can bill under Medicare Part B for services like lab tests and doctor visits. HOPPS regulations and other Medicare guidelines allow "incident to" services be billed to Medicare.

"Incident to" services are provided by non-physician practitioners like pharmacists and submitted under the physician's National Provider Identifier (NPI) number. They are called *incident to* because they are provided after physician evaluation or for a Medicare-covered

service. The NPI is a unique 10-digit number issued to healthcare providers by the Centers for Medicare & Medicaid Services (CMS). Pharmacists can bill under physicians' NPIs if they are provided under those physicians' direct supervision. Examples of services that can be billed to Medicare for pharmacist services include²:

- Diabetes self-management training for individuals or groups
- Office visits incident-to-physician
- Transitional care management incident-to-physician
- Medication therapy management services of various types
- Initial and subsequent Medicare annual wellness visits

Compensation for these visits requires pharmacists to be located either in a physician's office or hospital outpatient clinic. Regulations differ for incident-to billing in a physician-based outpatient clinic versus hospital-based outpatient clinics. Details are beyond the scope of this chapter and are continually changing. Readers are directed to the CMS and ASHP websites for details.

Reducing Overall Healthcare Costs

Pharmacists can also make a business case for ambulatory services by showing how those services reduce overall healthcare costs. A case might argue that pharmacist costs can increase as long as they are offset by greater cost reductions in other parts of the health-care system. Pharmacists' influence over the medication budget and institutional medication use gives them a variety of opportunities to lower costs including savings from interventions to reduce medication costs, lower medication-related healthcare costs, and help institutions to receive performance incentives.

REDUCE MEDICATION COSTS: Pharmacists can help institutions reduce medication expenditures by aiding physicians in choosing the most economical prescribing options for patients. Pharmacists are more knowledgeable about the costs of drugs and can monitor medication use and nudge physicians to choose the most cost-effective options to prescribe. A critical tool in lowering medication expenditures is the formulary system, which controls the institutions' purchase, dispensing, administration, and prescribing of medications. Pharmacists are crucial in managing and maintaining formulary systems that contain prescribing guidelines and best practices for all areas of the medication-use system. Formulary systems help ensure that prescribing choices are based on consensus evaluations of the effectiveness, safety, and costs of medications.

Pharmacists can also help reduce medication costs by taking full advantage of the 340B program. Because purchased drugs cost much less under the 340B program, hospitals can use the discounts to reduce medication prices for prescriptions filled in their outpatient pharmacies. These savings can be passed on to patients or kept by the pharmacy. Ensuring that eligible patients get the discounts can result in significant savings to institutions and patients.

REDUCE MEDICATION-RELATED HEALTHCARE COSTS: In addition to medication costs, pharmacists can help reduce avoidable healthcare costs due to underuse, overuse, and misuse of medications. These costs include preventable emergency department visits, physician appointments, hospital admissions, and other medication-related costs. Potential services associated with reducing or avoiding costs in other parts of the healthcare system include disease state management services, therapeutic monitoring, pharmacokinetic dosing management, targeted drug programs, medication therapy management, and patient education and wellness programs. These programs can help patients receive better health outcomes at reduced costs.

However, it is difficult to justify pharmacist services based on the argument of cost avoidance because savings figures are typically “soft,” meaning that they are not easily quantifiable. It is difficult to quantify cost savings associated with an event that did not happen (e.g., thromboembolic event avoided) and something a pharmacist did (e.g., anti-coagulation management). Another difficulty linking cost savings of pharmacist interventions relating to improved health consequences is the fact that many outcomes occur years in the future. The longer the time to outcome, the harder it is to attribute the outcome to pharmacists. Consequently, hospital administrators may give little credit for soft cost-avoidance savings. Fortunately, some new Medicare initiatives that impose financial penalties on providers who do not achieve specified metrics have helped pharmacists.

MISSING FEWER PERFORMANCE INCENTIVES: The CMS Hospital Readmissions Reduction Program is one such program that penalizes hospitals that have high readmission rates for conditions such as acute myocardial infarction, pneumonia, and heart failure. Pharmacists still face a challenge linking an ambulatory care pharmacist’s contribution to the reduction in financial penalty incurred by a hospital. However, readmissions need to occur within 30 days of discharge making it easier to link pharmacist services to the events. When linked to pharmacist services, the dollars saved by avoiding financial penalties are hard numbers that can be used to justify additional pharmacists or expanded programs.

The Affordable Care Act offers other opportunities for ambulatory pharmacists through new funding models other than traditional fee-for-service models. The Affordable Care Act’s other opportunities include:

- **Pay-for-performance (P4P)** — P4P is defined as a payment or bonus for achieving some specified performance goal.⁹ Pharmacy examples of P4P include achieving goals for medication adherence through the **Medicare Star Rating Program** or incentive programs established with local employers.
- **Pay-for-coordination** — In this model, pharmacists are paid for specified care coordination services to providers. Pay-for-coordination to pharmacists may be associated with patient-centered medical homes or care coordination services to patients as they transition from hospitals to community care.¹⁰
- **Value-based purchasing (VBP) programs** — VBP programs attempt to encourage health systems and other providers to consider cost and not just quality in the provision of care.¹¹ Private and public payers of healthcare link VBP compensation to pharmacies for their performance on generic substitution, therapeutic substitution (i.e., substituting different but therapeutically equivalent medicines), incentive-based formularies that encourage use of medications preferred by payers, and value-based insurance design that rewards providers who can enroll insured patients into disease management or wellness programs.

One incentive program of particular interest to ambulatory pharmacies is the **CMS Hospital Inpatient Value-Based Purchasing Program**. The program links payment incentives to four major dimensions of performance: clinical processes, patient outcomes, measures of efficiency, and patient experience. Measures for these four dimensions are described in **Table 14-2**.

A quick examination of the measures in Table 14-2 shows various opportunities for pharmacists. All eight clinical process measures are associated with medication use and can be influenced by pharmacists. Positive patient outcomes are also heavily associated with appropriate medication use. Pharmacists can positively shape the patient experience by improving service responsiveness, pain management, communication about medicines, and discharge information. Efficiency can be affected by helping reduce hospital readmissions and medication costs.

TABLE 14-2.**Performance Measures Associated with CMS Hospital Inpatient Value-Based Purchasing Program****Clinical Processes**

- Acute myocardial infarction (AMI) or heart attack are given fibrinolytic medication within 30 minutes of arrival
- Pneumonia patients given the most appropriate initial antibiotic(s)
- Surgery patients who were taking heart drugs called beta blockers before coming to the hospital, who were kept on the beta blockers during the period just before and after their surgery
- Patients who got treatment at the right time (within 24 hours before or after their surgery) to help prevent blood clots after certain types of surgery
- Surgery patients who are given the right kind of antibiotic to help prevent infection
- Surgery patients whose preventive antibiotics are stopped at the right time (within 24 hours after surgery)
- Surgery patients whose urinary catheters were removed on the first or second day after surgery
- Patients assessed and given influenza vaccination for preventive care

Patient Outcomes

- Acute myocardial infarction (AMI) 30-day mortality rate
- Heart failure (HF) 30-day mortality rate
- Pneumonia (PN) 30-day mortality rate
- AHRQ Patient Safety and Adverse Events Composite, known as PSI 90, a patient safety measure made up of a composite of 8 underlying safety measures (e.g., potentially preventable complications)
- Central line-associated bloodstream infection (CLABSI)
- Catheter-associated urinary tract infection (CAUTI)
- Surgical site infection (SSI)

Patient Experience (as measured by the Hospital Consumer Assessment of Healthcare Providers and Systems [HCAHPS] patient satisfaction survey)

- Communication with doctors
- Communication with nurses
- Responsiveness of hospital staff
- Pain management
- Communication about medicines
- Discharge information
- Cleanliness and quietness of the hospital environment
- Overall rating of care

Efficiency

- Medicare payment per beneficiary episode that spans from 3 days prior to an inpatient hospital admission through 30 days after discharge

Source: Centers for Medicare & Medicaid Services. The Hospital Value-Based Purchasing (HVBP) Program. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HVBP/Hospital-Value-Based-Purchasing.html>. 2015. Accessed January 1, 2015.

Making a business case for pharmacy ambulatory services requires leaders to understand which compensation and cost-saving strategies they can use to gain the support of potential internal and external stakeholders (**Table 14-3**). These benefits need to exceed the costs of providing them to achieve a positive ROI. Any program that generates a positive ROI has a good business case for being sustainable over time.

TABLE 14-3.
Variables Influencing the Business Case Made by Pharmacists for Ambulatory Services

COSTS	
Costs of providing ambulatory pharmacy services	Salaries and benefits (pharmacists, technicians, clerical, IT professionals) Medications and supplies Overhead (building space, utilities, hardware, software, licenses)
BENEFITS	
Revenue from ambulatory pharmacy services	Additional dispensing revenue Direct billing to insurers and patients Billing incident to physician services
Costs saved to overall healthcare system from pharmacy services	Reducing medication costs (formulary management, 340B purchasing) Lowering “soft” medication-related healthcare costs (events avoided) Missing fewer performance incentives (Medicare Star Ratings, contracts with patient-centered medical homes, value-based purchasing programs)

IT: information technology

WRITING A BUSINESS PLAN

A **business plan** is a more detailed version of a business model described in the beginning of this chapter. It lays out the steps for implementing the business model. In many cases, it is useful to flesh out the details of a business model before starting on the business plan. For instance, the business plan will revolve around the value proposition of the ambulatory pharmacy initiative, so there should be some idea of the value provided to the services’ primary customers. **Table 14-4** offers examples of outpatient pharmacy service value propositions that can be made to three different audiences: administrators, employees, and clinic and discharge patients. Note how these value propositions are tailored to the different needs of each audience, but they share common core messaging about the services provided.

The business plan tells a story about a new ambulatory pharmacy initiative. Its purpose is to interest, inform, and persuade stakeholders. All business plans tell the same basic story by answering three questions⁴:

1. What problem is the plan solving for the reader?
2. What solution is being proposed to solve the reader’s problem?
3. Why is the proposed solution the best option for solving the problem?

KEY POINT . . .

Value propositions often vary depending on the audience being persuaded.

. . . SO WHAT?

Perceptions of value depend on an individual’s perspective. An administrator might focus more on costs in determining value than a clinician who may focus on clinical outcomes. Patients may care about costs but only those paid out of pocket. They may also care about different clinical outcomes than clinicians (e.g., ability to eat favorite foods versus weight control). The solution is to tailor value propositions to the intended audiences. More than one value proposition may be needed.

TABLE 14-4.**Value Propositions for Providing Outpatient Pharmacy Services****For administrators**

Outpatient Pharmacy Services

Convenient onsite delivery of pharmacy services to patients

- Captures revenue that was previously lost to outside providers
- Expands institutional services from emergency department admission to post-discharge prescriptions
- Improves medication adherence of patients and reduces hospital re-admissions

For employees

Outpatient Pharmacy Services

Convenient onsite pharmacy services for you and your family

- Discounts on your medications
- Ability to drop off prescriptions before work and pick them up afterward
- Improved management of your lifestyle and health conditions

For clinic and discharge patients

Outpatient Pharmacy Services

Convenient onsite pharmacy services for you

- Discounts on your medications
- Easy access so no need to visit an out-of-the-way pharmacy after visiting your doctor or after hospital discharge
- Improved management of your lifestyle and health conditions

Because these three questions revolve about the needs of specific audiences, business plans vary depending on the audience and the plan's purpose. A plan written for a physician group's approval might differ in detail and focus from one directed at gaining financial backing from the chief financial officer (CFO). The right business plan is one that achieves established objectives and should be written with that in mind. Although there are many templates for writing business plans and no specific format, good business plans answer the three questions in a compelling manner using the following elements*:

- **Executive summary** — The executive summary provides an introduction to the plan and summarizes its major features and details.
- **Introduction and background** — These sections make a case that there is a need for the service and then back up those reasons with an analysis of the environment.
- **Product or service description** — This section provides details about the intended ambulatory services to be offered, their main features, how they will be delivered, and any other crucial details.
- **Pharmacy's operation** — Specific background is given about the ambulatory pharmacy where the service will be provided. This might include its portfolio of services and products and specific information about key personnel in the pharmacy.
- **SWOT Analysis** — This section delineates the strengths and weaknesses of the pharmacy organization as well as the opportunities and threats in the market environment (see below for more discussion of SWOT).
- **Marketing plan** — The marketing plan typically discusses the primary customer segments targeted for the services, how they will be served, the messaging promotional media for communicating with them, and an estimate of the potential

customers available to be served. It might also present the value proposition and how it exceeds what is currently available in the market.

- **Financial plan** — This section provides relevant financial details like costs, pricing, and revenues of the business. This is typically explained in financial statements of forecasted or estimated yearly sales, estimated net income, and break-even points.
- **Implementation plan** — This section discusses the most important things needed to successfully implement the program. This might include new software, changes in workflow, shifting greater responsibilities to the technicians, and remodeling the pharmacy. It should also include **key performance indicators (KPIs)**, which will be used to measure the success of the service described in the plan.

A detailed discussion of business plans is beyond the scope of this chapter. However, plans can be concisely summarized by the following steps:

- **Step one** — Analyze the business environment for opportunities and threats.
- **Step two** — Assess the fit of the pharmacy's resources and capabilities to the business environment.
- **Step three** — Choose a course of action.
- **Step four** — Fine tune the plan.

Step One: Analyze the Business Environment

This analysis assesses the way things are and future trends. It uses some sort of organized analysis like a **needs assessment** or SWOT analysis. A *needs assessment* is a systematic process to identify gaps between existing conditions and what is desired. Needs assessments often focus on *key performance indicators (KPIs)*, which are measures collected and used to evaluate the quality of institutional performance. A needs assessment starts with an analysis of KPIs associated with medication use in the institution. Examples of ambulatory pharmacy KPIs are:

- Time from presenting a prescription to dispensing
- Percentage of patients enrolled in disease management programs
- Average revenue generated per pharmacy employee

The gap between current circumstances and what is desired should be the stimulus for change. For example, an ambulatory pharmacy may offer medication reconciliation to inpatients who are being discharged from the hospital. The three KPIs associated with medication reconciliation might be the (1) proportion of patients who receive medication reconciliation, (2) number of discrepancies identified, and (3) number are discrepancies resolved. When linked to other KPIs such as the number of early readmissions to the hospital for drug-related problems and total financial penalties from payers for early readmissions, momentum to improve medication reconciliation services can occur.

Step Two: Assess the Pharmacy's Resources/Capabilities to the Business Environment

Another common tool to analyze the business environment is a SWOT analysis. The SWOT is an analysis of the strengths (**S**) and weaknesses (**W**) of the pharmacy or institution and an evaluation of opportunities (**O**) and threats (**T**) in the business environment. Information from this SWOT analysis is used to guide the rest of the business plan. The S and W of the SWOT analysis assesses the pharmacy's resources—its strengths and weaknesses under current conditions. The O and T evaluate current conditions in which the pharmacy operates.

SWOT analyses are generally conducted before any major pharmacy initiative. The goal is to use the SWOT to identify what initiatives will be most successful given the pharmacy's limited resources. **Table 14-5** shows an example of a SWOT analysis for the expansion of pharmacy ambulatory services.

TABLE 14-5

SWOT Analysis Example for the Expansion of Pharmacy Ambulatory Services

Strengths	Weaknesses
<ul style="list-style-type: none"> ■ Support of hospital administration ■ Highly trained and motivated pharmacy staff ■ High patient satisfaction scores for current ambulatory care pharmacy services 	<ul style="list-style-type: none"> ■ Staff is already working at capacity ■ Information systems need upgrading ■ Physical space for expansion is limited
Opportunities	Threats
<ul style="list-style-type: none"> ■ Hospital leaders have targeting early readmissions to hospital as a big problem ■ Physicians have expressed interest in coming up with interprofessional solutions to medication use 	<ul style="list-style-type: none"> ■ Other departments in the institution are competing for the same limited resources as the pharmacy ■ It may not be possible to link pharmacy interventions to a positive and measurable return on investment

Step Three: Choose a Course of Action

Based on the analyses in steps one and two, a course of action is taken. A bias toward implementing a new program or initiative is common in most business settings, but a conscious choice not to act might be a prudent action, too, given the needs assessment and SWOT analysis. Most important is the ability to defend a course of action to stakeholders. Essential to this effort is to describe the ambulatory service initiative in a meaningful way to audiences. They may not be familiar with the details of medication therapy management or other innovations, so pharmacists must provide sufficient details to make their potential value clear. At a minimum, a description of the service should be provided along with its main features, benefits, and channels of delivery (e.g., face-to-face, website).

Step three makes up the bulk of the business plan. It includes a description of the operations and the plans for marketing, financing, and implementation. If appropriate, visual documents like a flow chart or other form of process map might be included to describe the steps or elements of the business plan. Support for the plan is also important. Citations from the literature or descriptions of conversations with experts might be used to support choices made in a business plan. They can provide proof points that can strengthen the quality and credibility of the plan.

Step Four: Fine Tune the Plan

The business plan is the proposal for providing **sustainable services**. However, the plan often evolves as new things are learned through the implementation process. This means that that business plan may need continual refining and testing. One of the best ways to fine tune the business plan is through pilot testing. For patients, this might mean offering a service on a limited basis or in a pilot program. For administrators, it might consist of pitching the plan for feedback and comments. These steps can test the viability of and support for the service before putting too much money into it. In addition, the experience can be used to tweak the idea or make major pivots in how the services are offered.

A feedback and control system needs to be built into any plan to provide data to evaluate its success and identify suggestions for improvement.⁴ This feedback system should be explicit about measures of success or failure. Measures of successful ambulatory pharmacy services might consist of the total number of patients who use the service, **revenue** collected from the service, and patient satisfaction. It is critical to identify the minimum number of easy-to-collect measures that can validly determine the success of the program.

When it is time to evaluate a program, a decision can be made to continue the program without changes, cancel the program, or make changes. Changes can include expansion of programs, contraction of programs, or adjustments designed to improve programs. Without a feedback loop and method for deciding whether to continue with an ambulatory service, a program can limp along, draining pharmacy resources that can be used better elsewhere. Sometimes it is better to pull the plug on an initiative and move on to something better.

KEY POINT . . .

Business models and plans should adapt to the reality of circumstances. They are not written in stone and should be constantly reassessed and retooled as needed.

. . . SO WHAT?

Each element of a business plan is just a best guess about what will happen when a new service is offered.

Even for established services, there is no guarantee that what worked in the past will work the same way in the future. Like any blueprint, it may need to be adjusted as ideas and assumptions are tested. Things that do not work need to be changed, and things that work better than expected should be done more often.



SUMMARY

The market for ambulatory pharmacy services is dynamic and strengthens prospects for the expansion of pharmacist services. Healthcare reform and the push for cost control have opened the door for pharmacists to provide financially sustainable services.

Future developments might offer additional opportunities. Potential developments include more widespread use of patient-centered medical homes, expansion of P4P initiatives like the Medicare Star Rating program, greater use of value-based-purchasing, and most importantly, provider recognition for pharmacists under Medicare Part B and state Medicaid programs. No matter what occurs in the future, however, the growth of sustainable ambulatory pharmacy services depends on the ability of pharmacists to effectively articulate their value proposition to key stakeholders and to back up that proposition with performance that impacts care.

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CHAPTER REVIEW QUESTIONS

1. _____ is the term that describes what a healthcare provider receives for doing a job.

- a. Cost
- b. Charge
- c. Compensation
- d. Revenue

Answer: c. Compensation. Compensation is what a healthcare provider is actually paid for doing a job.

2. _____ describes how much benefit is received for a service compared to how much it costs to provide.

- a. KPI
- b. ROI
- c. SWOT
- d. CFO

Answer: b. ROI. ROI is a ratio of benefits to costs. A positive ROI means that more benefits are produced than the costs of producing them.

3. This is the federal program that allows eligible hospitals and other healthcare institutions to purchase outpatient drugs at significantly reduced prices from drug manufacturers.

- a. 340B Drug Pricing
- b. Hospital Inpatient Value-Based Purchasing Program
- c. Pay-for-Performance
- d. HCAHPS

Answer: a. 340B Drug Pricing. This program is the federal initiative that allows eligible healthcare institutions to purchase outpatient drugs at significantly reduced prices and sell them to covered patients.

4. Which of the following statements is true?

- a. Pharmacists are recognized as healthcare providers by the Social Security Administration.
- b. Incident to services can be billed to Medicare for any pharmacist service if submitted under a physician's National Provider Identifier (NPI) number.
- c. Health insurance companies are not required by law to pay bills submitted by pharmacists for most non-dispensing services.

Answer: c. Health insurance companies. They have no legal obligation to pay bills submitted by pharmacists for non-dispensing services because pharmacists are not recognized by the Social Security Administration as healthcare providers.

5. Which of the following programs follow the traditional fee-for-service payment model?

- a. 340B Drug Pricing program
- b. Hospital Inpatient Value-Based Purchasing Program
- c. Medicare Star Rating program

Answer: a. The 340B Drug Pricing Program. It follows the traditional fee-for-service model that pays pharmacists for the number of prescriptions they dispense. The 340B program allows the drugs dispensed to be purchased at lower prices, but there is no link of payment to the quality of services provided.

6. A _____ is the argument made to potential internal and external stakeholders that the benefits of an ambulatory service exceed the costs of providing it. It is often made by showing that the service achieves a positive ROI.
- Value proposition
 - Business plan
 - Business model
 - Business case

Answer: d. A business case. In a financial argument, it is designed to convince decision makers and other stakeholders to support new or expanded ambulatory services.

7. A _____ describes the value proposition made to customers, the resources and processes used to create the value proposition, and the profit formula for generating sufficient revenues to cover the costs of providing the customer value proposition over time.
- SWOT analysis
 - Business plan
 - Business model
 - Business case

Answers: b and c. The business model is a rough outline of what goes into the business plan. The business plan provides a detailed description of the value proposition, resources and processes, and profit formula.

8. A(n) _____ value proposition centers on offering convenience to patients. It highlights things like nearby locations, fast service, liberal hours of operation, home delivery, 24-hour access to pharmacists via telephone or online services, and other conveniences.
- Economic
 - Emotional
 - Functional

Answer: c. Functional. A functional value proposition offers convenience by finding the right solutions for customers with as little time and as little physical and cognitive effort as possible.

9. Which performance measures associated with the CMS Hospital Inpatient Value-Based Purchasing Program can be influenced by pharmacist services?
- Clinical processes
 - Patient outcomes
 - Patient experience
 - Efficiency
 - All of the above.

Answer: e. All of the above. Pharmacist services can influence all performance measures.

10. The _____ is a pharmacist who takes ownership for the success of a pharmacy initiative. This individual may or may not have a formal title.
- Director of pharmacy
 - Ambulatory pharmacy manager
 - Clinical pharmacy coordinator
 - Pharmacist champion

Answer: d. The pharmacist champion. He or she is a formal or informal leader who is key to the success of any pharmacy initiative.

CHAPTER DISCUSSION QUESTIONS

- What will it take for pharmacists to receive formal recognition as healthcare payers?
- Why do pharmacists need to understand the costs of providing ambulatory care services?
- List various ways that pharmacists can make a business case for ambulatory care services.
- Discuss the general opportunities and threats to ambulatory pharmacy services in health-care systems.
- Identify an ambulatory pharmacy service and develop a value proposition for it.

CHAPTER 15

Sterile Preparations and Admixture Programs

Ryan A. Forrey and Philip J. Schneider

LEARNING OBJECTIVES

After completing this chapter, readers should be able to:

1. List national standards that apply to compounding sterile preparations.
2. Differentiate among uses of laminar airflow workbenches, biological safety cabinets, and compounding isolators.
3. Discuss the importance of a buffer room to compounding sterile preparations.
4. Describe how a person should cleanse and garb before compounding sterile preparations.
5. List the information that must appear on a label for a compounded sterile preparation.

KEY TERMS AND DEFINITIONS

- **Active pharmaceutical ingredient (API):** Any pharmacologically active substance or mixture of substances intended to be used in the compounding of a drug preparation.
- **Ante area (or anteroom):** An ISO Class 8 or better air quality area where personnel perform hand hygiene and garbing procedures, staging of components, order entry, compounded sterile preparation (CSP) labeling, and other high particulate-generating activities.
- **Aseptic technique:** The methods used to manipulate manufacturer-supplied sterile products so that they remain sterile as CSPs.
- **Beyond-use date (BUD):** The date or time beyond which a compounded preparation cannot be used and must be discarded. The date or time is determined from the date or time when the preparation was compounded.
- **Biological safety cabinet (BSC):** A primary engineering control (PEC) device that is a ventilated cabinet for CSPs, personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.
- **Buffer area (or room):** The area where the PEC is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding CSPs.
- **Clean room (or buffer room):** A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.
- **Closed-system drug-transfer device (CSTD):** A drug-transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system.
- **Cold storage conditions (refrigerator):** 2°–8°C (36°–46°F).

- **Components:** The individual ingredients, containers, and closures that are used to compound sterile preparations.
- **Compounded sterile preparation (CSP):** A dose or doses of medication that are prescribed for a patient(s) that must be prepared for administration and be sterile.
- **Compounding aseptic containment isolator (CACI):** A PEC that protects workers from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes while also providing an aseptic compounding environment. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial-retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed 100% by properly designed building ventilation.
- **Compounding aseptic isolator (CAI):** A PEC that is a form of isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial-retentive filter (HEPA minimum).
- **Containment primary engineering control (C-PEC):** A ventilated device designed and operated to minimize worker and environmental exposures to hazardous drugs by controlling emissions of airborne contaminants.
- **Containment secondary engineering control (C-SEC):** The room with fixed walls in which the C-PEC is placed. It incorporates specific design and operational parameters required to contain the potential hazard within the compounding room.
- **Containment segregated compounding area (C-SCA):** A type of room in which the C-PEC for compounding hazardous drugs is placed that meets only minimal room pressurization and air exchange requirements. Sterile preparations compounded in a C-SCA have a shorter BUD.
- **Critical site:** A location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room, HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. Risk of microbial particulate contamination of the critical site increases with the size of the openings and exposure time.
- **Direct compounding area (DCA):** A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air; also known as first air.
- **First air:** The air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.
- **Garb:** Clothing worn by personnel during the compounding of sterile preparations to minimize particulates being shed from body and clothing into the buffer room and PEC.
- **Hazardous drugs (HDs):** Drugs that are classified as hazardous if studies in animals or humans indicate exposure to them has potential for causing cancer, developmental or reproductive toxicity, or harm to organs.
- **Laminar airflow workbench (LAFW):** A PEC that is a controlled environment created by a HEPA filter to retain airborne particles and microorganisms. Its use decreases the chance of microbial contamination during the compounding of sterile preparations.
- **Media-fill test:** A test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile product without microbial contamination. During this test, a microbiological growth medium

such as Soybean–Casein Digest Medium is substituted for the actual drug product to simulate admixture compounding.

- **Negative-pressure room:** A room that is maintained at a lower pressure than the adjacent areas; therefore, the net flow of air is into the room.
- **Positive-pressure room:** A room that is maintained at a higher pressure than the adjacent areas; therefore, the net flow of air is out of the room.
- **Primary engineering control (PEC):** A device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSPs. Such devices include, but are not limited to, LAFWs, BSCs, CAIs, and CACIs.
- **Pyrogens (bacterial endotoxins):** Metabolic products of living microorganisms, or the dead microorganisms themselves, that cause a pyretic (rise in body temperature) response upon injection.
- **Risk levels**
 - **Low risk:** Preparation that involves only transferring, measuring, and mixing manipulations of not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the CSP.
 - **Low risk with 12-hour or less BUD:** Any preparation meeting the definition of low risk that is prepared in a PEC that is not located in an ISO 7 buffer area.
 - **Medium risk:** Multiple individual or small doses of sterile products that are combined or pooled to prepare a CSP, which will be administered either to multiple patients or to one patient on multiple occasions. Can also describe compounding that includes complex aseptic manipulations or compounding that requires an unusually long duration.
 - **High risk:** Preparation that contains nonsterile ingredients, including manufactured products not intended for sterile routes of administration (e.g., oral). Or a nonsterile device is employed before terminal sterilization. Or any of the following are exposed to air quality worse than ISO Class 5 for more than 1 hour: (1) sterile contents of commercially manufactured products; (2) CSPs that lack effective antimicrobial preservatives; (3) sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs. Or compounding personnel are improperly garbed and gloved. Or nonsterile water-containing preparations are stored for more than 6 hours before being sterilized. Or it is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendia specifications in unopened or in opened packages of bulk ingredients.
- **Secondary engineering control (SEC):** The ante area and buffer area (see definitions above).
- **Standard operating procedures (SOPs):** A set of instructions or steps someone follows to complete a job safely, with no adverse impact on the environment (and which meets compliance standards), and in a way that optimizes operational and production requirements.
- **USP Chapter <797>: Pharmaceutical Compounding—Sterile Preparations:** A pharmacy-related general chapter in the *United States Pharmacopeia–National Formulary* that is among those chapters numbered below 1000 so as to be enforceable by the U.S. Food and Drug Administration (FDA), The Joint Commission, and some State Boards of Pharmacy.
- **USP Chapter <800>: Hazardous Drugs—Handling in Healthcare Settings:** A general chapter in the *United States Pharmacopeia–National Formulary* that is among those chapters below 1000 so as to be enforceable by the FDA, The Joint Commission, and some State Boards of Pharmacy.



INTRODUCTION

Patient safety is a crucial component to patients receiving the most benefit from their medications. Pharmacists have historically played a critical role in protecting patients from harm that may result from drug therapy. Increased attention has been devoted to the use of high-risk medications—those that have the greatest potential to cause adverse drug events when used. High-risk medications are most commonly defined according to drug toxicity but may also be defined by the route by which they are administered. Focusing on both high-risk medications and high-risk methods of administering these medications can narrow the scope of work.

There is an excellent chapter “High-Alert Medications: Safeguarding against Errors” in the text *Medication Errors*.¹ Sixteen medications or drug categories are listed, 14 of which can or are administered by the intravenous (IV) route. Kaushal et al. found that the IV route of administration was the most common in medication errors detected in pediatric inpatients.² In one of their annual reports, the United States Pharmacopeia (USP) reported that “the intravenous route of administration often results in the most serious medication error outcomes” based on the reports submitted to MEDMARXSM.³ We do not need a formal failure mode analysis to know that IV drug administration is a high-risk area of medication use and needs the full attention of pharmacists and other healthcare providers.

The IV route of administration bypasses three physiologic safeguards—the gut, liver, and skin. The gut may break down medications before they are ever absorbed, or the drug may not even be absorbed through the gastrointestinal tract. The liver protects patients from many toxic doses of medications and can safeguard patients through the first-pass effect when medications are administered orally. The skin protects patients from infections that might be caused by pathogenic microorganisms in the environment, especially the hospital. Thus, preventable adverse medical events resulting from medications administered by the IV route may result from infections from contamination, toxicity from the medicine, or both.

Reports about problems with the safety of IV drug therapy were documented in the late 1960s. Patterson et al. expressed concerns about drug incompatibilities and the length of time between preparation and administration of medications prepared at the bedside after finding that 60% of IV fluids used at their hospital contained more than one drug, and many were administered more than an hour after preparation.⁴ These authors recommended that the pharmacy assume responsibility for compounding IV admixture doses to resolve these problems. Flack et al. reported being asked for “technical help from the pharmacy service” by the surgeons investigating the effectiveness and safety of parenteral nutrition to resolve problems of contamination and incompatibilities with the formulas that were being “hand mixed in open laboratory surroundings.”⁵

Thur et al. observed nurses preparing parenteral admixtures in patient care areas and reported an error rate of 21%. The rate of wrong doses prepared was 9%, incompatible drugs mixed was 6%, wrong drug or solution used was 3%, and preparation of drugs not ordered was 3%. Deviations from accepted sterile technique were observed, with counters not being cleaned (99%), hands not washed (97%), touching sterile areas of the IV container (47%), and vial or bottle tops not being cleaned (31%).⁶ O'Hare et al. used a disguised observer method to evaluate error in preparation and administration of IV medications by physicians and nurses. They found that physicians made at least one error in 98% of the doses prepared, and 83% of these doses were administered by nurses.⁷ Taxis and Barber also observed nurses who prepared and administered IV drugs on 10 wards in a hospital

in the United Kingdom. Of 249 errors identified, at least 1 error occurred in 212 of the 430 doses observed. Most errors occurred when bolus doses were prepared and administered or for doses requiring multiple steps to prepare. One strategy recommended was to decrease errors by reducing the amount of preparation on the ward.⁸

Even if properly ordered, errors can occur in preparation that can cause harm to patients. Thompson et al. evaluated the concentrations of admixed medications delivered to patients and found evidence of incomplete mixing of medications in IV solutions prepared at the bedside. They also found that there was more uniformity of concentrations of potassium chloride when these doses were prepared in the pharmacy.⁹ Calculation errors are also a root cause of error in preparing medications. Perlstein et al. found that one of 12 doses calculated by nurses had an error, resulting in a tenfold dose compared to that ordered. Pediatricians made errors in one of 26 computations. Pharmacists made fewer errors than nurses and physicians.¹⁰

As a result of these reports, pharmacy-based centralized IV admixture programs have emerged as a fundamentally safer medication-use system. According to ASHP National Surveys of Pharmacy Practice in hospital settings, this system has been shown to be present in the vast majority of U.S. hospitals. In 2008, only 10% of U.S. hospitals relied on nurses to prepare IV medications as the primary method. Most hospitals used the minibag system (i.e., small volume parenterals; see Chapter 16) to administer medications by the IV route, and doses are prepared in the pharmacy.¹¹

In spite of this, there is some evidence that complacency can arise in pharmacies undermining the potential benefits of a pharmacy-based IV admixture program. Sanders et al. reported that pharmacists had an error rate of 7.24% and a contamination rate of 7%.¹² These errors and contamination rates were higher than that observed for pharmacy technicians. Pharmacists made fewer errors and contaminated fewer IV preparations when they knew they were being observed, suggesting the emergence of complacency and the need for continuing vigilance. Flynn et al. also reported high error rates in pharmacy-based IV admixture programs. They found an error rate of 9% in five hospital pharmacies studied using an observation-based method.¹³ Trissel et al. evaluated the aseptic technique of pharmacists and technicians when compounding complex USP medium-risk sterile preparations using **media-fill tests**. Pharmacist compounding resulted in a contamination rate of 4.4% compared to a rate of 6.2% for technicians. The overall contamination rate was 5.2%.¹⁴

Recent reports of patients harmed by pharmacy-compounded sterile medications, including IV admixtures, have resulted in public concern about patient safety. According to the PEW Charitable Trusts in their drug safety project, since 2001 there have been 25 reported compounding errors or potential errors associated with 1,049 adverse events, including 89 deaths. Contamination of sterile preparations was the most common error reported. They suggest that since many events are unreported, this is an underestimate of the occurrence.¹⁵ The highly publicized events resulting from unacceptable practices and environmental conditions at the New England Compounding Center facility, including 64 deaths, has resulted in renewed

KEY POINT . . .

USP Chapter <797> Pharmaceutical Compounding—Sterile Preparations establishes a national enforceable standard for compounding both nonhazardous and hazardous sterile preparations.

. . . SO WHAT?

This document guides much of the activities for handling sterile preparations. Failure to follow the recommendations could lead to problems with accreditation and licensing.

public and regulatory concern about the quality of sterile preparations compounded in pharmacies.¹⁶ The publication of enforceable standards, **USP Chapter <797>**¹⁷ and **USP Chapter <800>**,¹⁸ and attention to this by The Joint Commission (TJC) and State Boards of Pharmacy mandates that pharmacists take responsibility for competently compounding sterile preparations. The intent of this chapter is to summarize the requirement for doing this.

QUALITY ASSURANCE IN COMPOUNDING STERILE PREPARATIONS

Preparations to be used for parenteral, ophthalmic, and irrigation purposes must be free from chemical and physical contaminants, accurately and correctly compounded, sterile and free of **pyrogens**, stable until their **beyond-use date (BUD)**, and properly packaged and labeled for use.

Components

The majority of **compounded sterile preparations (CSPs)** are comprised of **components** that are clean, sterile, and pyrogen-free as purchased from pharmaceutical manufacturers. High-risk compounding involves the use of components that are not sterile and may not be pyrogen-free. The extemporaneous compounding of concentrated morphine sulfate injection from the powder is an example. In high-risk compounding, it is essential to use a USP grade chemical or obtain a certificate of quality analysis from the supplier of the chemical, because the pharmacy is usually not equipped or qualified to perform chemical analyses. Assuming that the certificate is judged to be reliable and the substance meets acceptable standards, like those of the USP, the pharmacist can take responsibility for compounding with the chemical.

Compounding policies and procedures (i.e., **standard operating procedures [SOPs]**) must be developed so that the final preparation meets the standards required for a sterile preparation including sterility, freedom from pyrogens, and an acceptable particulate level. For high-risk preparations, the pharmaceutical characteristics must be produced as a consequence of the compounding and processing steps. Sterility must be achieved, usually by appropriate filtration, through sterile, disposable, nonreactive, 0.2-micron porosity membrane filter devices. During filtration, particulate matter is removed to very low levels, below visible sizes, rendering the solution clear. Removing pyrogens is more difficult; the best approach is to obtain raw materials that are free from pyrogens as supplied.

For low- and medium-risk preparations, ensuring that the preparation has the required characteristics is primarily a matter of maintaining the quality level that the commercial manufacturer built into the product.

Compatibility and Stability

Responsibility for the compatibility and stability of formulated preparations rests with the pharmacist. Detailed compatibility and stability information may not be readily available for high-risk compounding. Lacking the facilities to perform research and testing, pharmacists are challenged to draw on their basic chemical and physical knowledge, experience in compounding, and awareness of available literature resources. Probably the most widely used reference is the ASHP *Handbook on Injectable Drugs*.¹⁹ Other information may be available from the commercial supplier of a component and from other literature resources.

Unexpected compatibility problems may be visible immediately or within a few hours after compounding, but not all incompatibilities are visible. All incompatibilities affect the stability of a preparation. However, stability considerations are broader and include overall assurance that the activity and chemical/physical integrity of the formulation is maintained until the preparation is administered to a patient.

Batch Formulas and Records

Batch compounding of CSPs requires strict adherence to SOPs. Any failure in the process of compounding can lead to waste and/or pose a threat to patient safety. Master formula sheets and batch control records establish a uniform approach to the compounding process. The master formula sheet provides exact directions on the standard compounding of the batch preparation (**Figure 15-1**). The batch control record then documents the completion of these tasks and identifies that each step has been followed for each individual batch of CSPs.

KEY POINT . . .

A pharmacist is responsible for the stability and compatibility of CSPs and should be consulted when a CSP is made outside the pharmacy.

. . . SO WHAT?

Just because a CSP might be compounded outside of the pharmacy does not mean that the pharmacist is no longer responsible for its impact on patient outcomes. Pharmacists need to ensure that processes are established and supported for ensuring stability and compatibility of compounded products.

ENVIRONMENTAL CONTROLS

The facilities and equipment in which the compounding of sterile preparations is performed must be designed and operated in a manner conducive to achieving/maintaining intended quality characteristics of the finished preparations.

Primary Engineering Controls

USP Chapter <797> requires that all sterile compounding, regardless of risk level, be done in an ISO Class 5 environment (i.e., fewer than 100 airborne particles larger than 0.5 microns per cubic foot) that is maintained in a horizontal **laminar airflow workbench (LAFW)**, a suitable **biological safety cabinet (BSC)**, or a suitable **compounding aseptic isolator (CAI)**.¹⁷ These are key engineering control devices designed to continuously sweep the **direct compounding area (DCA)** with high-efficiency particulate air (HEPA)-filtered air (i.e., **first air**). The 99.97% efficiency of a HEPA filter should render the air stream clean and approaching sterility. Still, this relatively slow airflow can easily be overcome with adverse air currents, even by the expelled breath from compounding personnel talking; thus, the DCA must be protected from inappropriate activities of personnel (to be discussed later). The HEPA filter should be protected from damage during use and its efficiency certified at least every 6 months. BSCs and **compounding aseptic containment isolators (CACIs)** must be used to maintain sterility of the preparation and to protect compounding personnel when **hazardous drugs (HDs)** are being compounded. These are discussed in more detail later in the chapter in the section specific to HD compounding.

KEY POINT . . .**Primary engineering control (PEC)**

devices provide the HEPA-filtered first air that bathes critical sites of syringes, needles, vial tops, and ampul openings to prevent microorganisms from entering the final CSP.

. . . SO WHAT?

Any barriers to the laminar flow of HEPA-filtered air can introduce the potential for contamination.

<p>Sterile Glycerin for Injection 100% 3 mL KEEP REFRIGERATED Lot No.: 08122007-01 Prepared by: VB/RDP Beyond-use Date: February 12, 2008 XYZ Pharmacy Department</p>	<p>Pharmacy Department <u>Master Formula Sheet</u></p>	<p>Attach Batch Label Here</p>
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Sample Label (above)

Preparation: Sterile Glycerin for Injection 100% **Control No:** 09182008-01 **BUD:** 3/18/2009

Equipment:

Peristaltic Pump—Baxa Repeater Pump Clean depyrogenated glass beaker, 500 mL Sterile tubing set—Baxa fluid transfer tube set no. 11 Sterile extension set—Baxa extension set no. 87	Hydrophilic filter—Baxa Supor capsule 0.2 micron filter (H938 24102 3) Sterile fluid dispensing connector—B. Braun No. 415080 Sterile disposable syringes, 6 mL and 60 mL Sterile latex-free Luer tip caps—Becton Dickinson
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Ingredient	NDC, Lot No. & Expiration	Ingredients	Amount	Measured by & date	Checked by & date
1		Synthetic Glycerin, USP	400 mL		
2					
3					

Procedure: (Caution: This is a high-risk sterilization procedure.)

1. Pour 400 mL of glycerin into a 500-mL clean depyrogenated glass beaker.
2. Working in appropriately cleaned compounding aseptic isolator, attach fluid transfer tube set to inlet end of filter. Attach extension set to outlet end of filter. Attach fluid dispensing connector to free end of extension set.
3. Place the free end of the fluid transfer tube into the beaker containing the nonsterile glycerin.
4. Place fluid transfer set tubing into the peristaltic pump.
5. Prime tubing by setting pump at lowest possible setting (low, 1). When glycerin reaches the filter, allow 100 mL to pass by the pump. Turn the pump off and allow the filter to become wet (about five minutes).
6. Continue to pump glycerin at lowest setting; a faster pumping rate will cause failure of tubing inside pump head.
7. After air is out of the tubing sets and filter, aseptically attach a 60-mL sterile syringe to the fluid dispensing connector.
8. Set pump for 500 mL. Remove and inspect the extension tubing around the pump head every 500 mL to make sure it is not stretched, as this will lead to tubing failure.
9. When approximately 50 mL of glycerin has filled the 60-mL syringe, remove syringe and fluid dispensing connector. Attach another clean sterile fluid dispensing connector to the extension set. Attach a clean, sterile 60-mL syringe to the fluid dispensing connector. Repeat procedure until all glycerin is filtered.
10. After glycerin is filtered, perform the filter integrity test on the used filter.
11. After the filter passes the integrity test, attach a 6-mL sterile syringe to the 60-mL syringe containing the filtered glycerin using the fluid dispensing connector. Fill syringe with 3 mL of sterile glycerin.
12. Aseptically place a Luer tip cap on all syringes.
13. Repeat filling process until all glycerin is packaged. Theoretical yield = 166 syringes; Actual yield = _____
14. Test sterility by USP Chapter <71> and visually test for color, clarity, particulate matter, and syringe integrity.
15. Perform bacterial endotoxin test according to USP Chapter <85>.
16. Label filled syringes. Quarantine filled syringes for 14 days under refrigeration.

Approved by: _____ **Date:** _____ **Time:** _____

FIGURE 15-1. Example of a master formula sheet.

Source: Originally published in McCluskey SV. Sterilization of glycerin. *Am J Health-Syst Pharm.* 2008; 65:1173-6. ©2008, American Society of Health-System Pharmacists, Inc. All rights reserved. Used with permission.

Secondary Engineering Controls

Because PECs draw air from the surrounding room, USP Chapter <797> requires a **buffer area** around these devices that meets ISO Class 7 (i.e., fewer than 10,000 airborne particles larger than 0.5 microns per cubic foot). Low- and medium-risk preparations may be compounded in facilities where there is no physical separation between the **ante area** and the buffer area. High-risk preparations require an anteroom separate from the buffer room. See schematics in **Figures 15-2** and **15-3**.

The surfaces of all ante and buffer area ceilings, walls, floors, shelving, cabinets, and work surfaces should be smooth, impervious, free from cracks and crevices, and nonshedding, making them easy to clean and disinfect. Junctions of ceilings to walls, walls to walls, and floors to walls should be coved (i.e., angled to prevent a crevice) or caulked to make them easier to clean. There should be no dust-collecting ledges, pipes, or similar surfaces. Work surfaces should be constructed of durable, smooth, and impervious materials, such as stainless steel or molded plastic. Carts should be of stainless steel wire or sheet construction with good quality, cleanable casters.

Clean airflow should be outward from the DCA through the buffer area, then through the ante area by means of cascading differential air pressures. These or similar structural design considerations, along with planned cleaning programs, disinfecting of all surfaces, and traffic control of personnel and supplies, make it possible to protect the direct DCA.

Cleaning and Disinfecting

Surface contamination can be expected, even within the LAFW, BSC, or compounding aseptic isolator (CAI). Therefore, written SOPs should be followed for cleaning and disin-

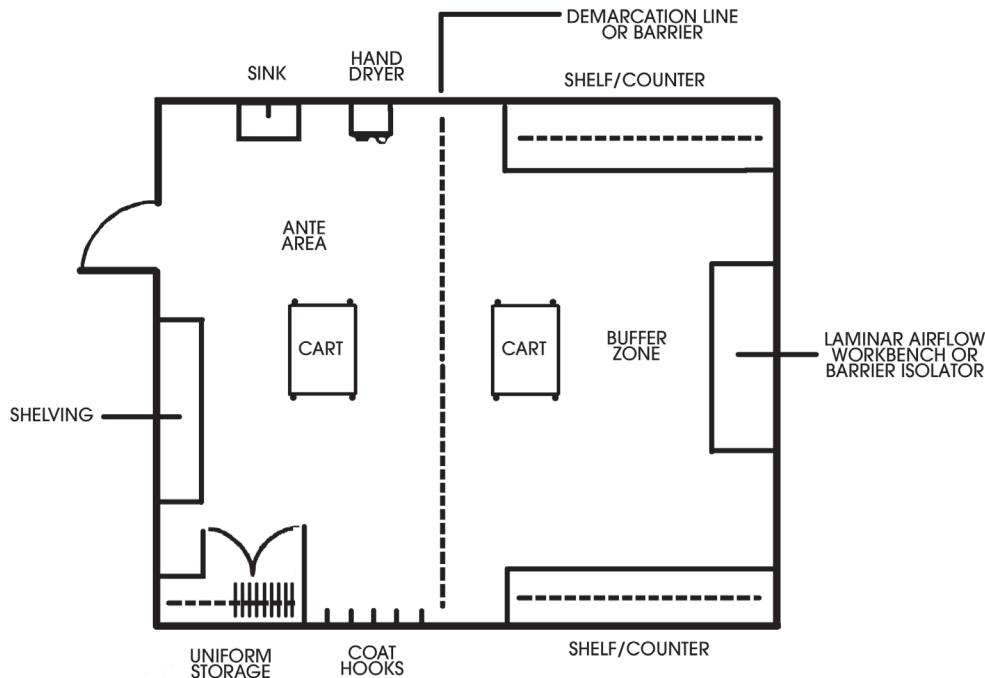


FIGURE 15-2. Schematic example of a clean room floor plan suitable for low- and medium-risk level compounded sterile preparations.

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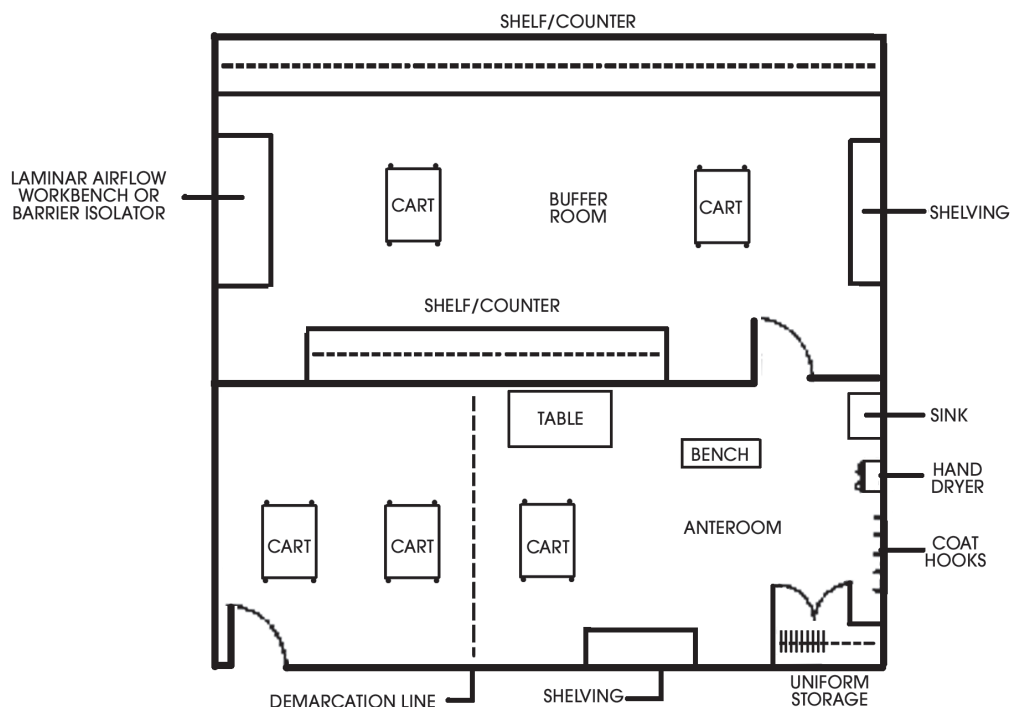


FIGURE 15-3. Schematic example of a clean room floor plan suitable for high-risk level compounded sterile preparations.

Source: Copyright © 2007, United States Pharmacopeial Convention. Used with permission.

fecting all surfaces within the ante and buffer areas. Cleaning of floors, walls, and ceilings should be performed with a mild detergent solution (i.e., “hospital disinfectant”) using a nonshedding, absorbent mop, wipe, or sponge. This should be followed by wiping work surfaces with an effective disinfectant like sterile 70% isopropyl alcohol (IPA). All shelving, supply carts, and countertops in the remainder of the ante and buffer areas should be cleared of supplies, cleaned, and disinfected in a similar manner at least monthly. Floors in these areas should be cleaned and disinfected daily, working from the cleanest area outward. All reusable cleaning tools should be restricted to use in the ante and buffer areas and thoroughly cleaned and sanitized after each use. Cleaning in the LAFW, BSC, or CAI should be done with a sterile, nonshedding wipe dampened with sterile 70% IPA.

Traffic Control

The flow of supplies and personnel through the ante and buffer areas must be rigidly controlled to prevent carrying contamination inward. No personnel should be allowed to approach the PEC device unless properly **garbed** and adequately trained. This includes

KEY POINT . . .

Secondary engineering controls provide a very clean environment within which the PECs work best.

. . . SO WHAT?

The best aseptic conditions consist of layers of engineering controls. If an aseptic environment exists within a very clean environment, chances of contamination are lessened.

housekeeping personnel. All supplies should be externally cleaned and disinfected during transition through the ante area to the buffer area.

An arrangement in which supplies are brought into the ante area external to the demarcation line is preferred (see Figure 15-3). At this point, they are unboxed, cleaned, disinfected, and transferred to a clean cart restricted to the buffer room. This step serves as a barrier to many of the natural contaminants on the outside of large volume parenteral (LVP) bags, vials, syringe pouches, transfer set packages, and other required supplies.

A further transfer barrier step should occur as supply items are introduced into the LAFW, BSC, or CAI. Whenever possible, an external wrap would be removed (e.g., peeling back syringe pouches) at the edge of the LAFW or BSC. Vials and other items not packaged in an outer wrap should be carefully disinfected by wiping with a wipe dampened with sterile 70% IPA. The supply items introduced into the PEC device should be limited to those required for the planned procedure and should be arranged so as not to obstruct the HEPA airflow pattern and to provide for efficient processing—that is, to the right and left of the work site in a horizontal LAFW and around the perimeter in a BSC or compounding isolator.

These barrier steps during the introduction of supplies should be recognized as only sanitizing, not sterilizing, steps and their effectiveness depends on the techniques of the operator. Any residual contaminants on the surfaces of supply items may be transferred to the sterile gloves of an operator and may be present for possible touch contamination transfer to the preparation. This risk of contaminating a preparation will increase progressively from low-risk to high-risk preparations.

Environmental Testing

Although all the elements so far mentioned, pursued with dedication, should provide a controlled environment, a testing program should be developed to verify that control is achieved and maintained. The focus of testing should be on detecting the presence of microbial contaminants in the environment. Both surface testing, for the deposit of microorganisms on exposed surfaces over time, and air-volume sampling, for microorganisms suspended in the air, should be performed. In principal, baseline (minimal) microbial counts should be determined when the environment is under control. A monitoring program should then be designed to detect loss of control evidenced by increases in the microbial counts. Such increases signal the need to determine the cause and correct it. The USP has a microbiologic evaluation process for **clean rooms** that should be considered.²⁰

KEY POINT . . .

People are the source of the most contamination in a sterile compounding environment; so minimizing the number of people and their movements within sterile compounding areas is essential to prevent contamination of CSPs.

. . . SO WHAT?

People are social animals who enjoy interacting with others. However, sterile compounding environments are not the place to do so.

COMPOUNDING PERSONNEL

Compounding personnel in the ante and buffer areas should be limited to those adequately trained and competency-tested for aseptic technique (to be discussed later) and to the minimal number required for the planned procedures. Because the human body is constantly shedding particles, many of which are viable microorganisms, major efforts

must be made to reduce the ingress of these particles into the buffer area but, particularly, into the DCA. This is accomplished by good personal hygiene—thorough washing and disinfecting of hands, donning garb to confine the particles as much as possible, and following good aseptic technique.

Training and Evaluating Compounding Personnel

To achieve good sterile compounding practice, personnel must be adequately trained; the effectiveness of the training must be tested by written exams, observation by trained personnel, media-fill testing, and fingertip glove testing. Training is the most significant factor contributing to the assurance of quality in sterile preparations, because personnel are recognized as the primary source of contaminants—both viable and nonviable—shed in the clean room environment. Therefore, compounding personnel must be taught to understand this natural phenomenon and how they can control particulate shedding while compounding. Considerable information regarding proper training will be found in ASHP's text and video programs on compounding sterile preparations.²¹⁻²⁴

Pharmacists and technicians who compound sterile preparations must understand good compounding practice and practice excellent aseptic technique. Training should make clear that sterile preparations must have the highest level of quality and purity of all dosage forms. Trainees should be instructed in the nature of contaminants and the means for achieving the required level of purity, maintaining stability during the required beyond-use dating of the preparation, and evaluating the required characteristics. Pharmacists should be sufficiently familiar with the principles of sterilization to work with technicians who perform autoclaving or hot-air sterilization of supplies or preparations. The validation of these processes for their bactericidal effect is highly critical and requires considerable expertise.

Although pharmacists and technicians are not expected to be engineers, they should know the specifications for facilities and devices in which they must perform. This includes the selection of equipment (for example, an LAFW) from external suppliers or working with in-house engineers to ensure proper clean airflow into the ante and buffer areas. An understanding of some engineering principles is needed to achieve required environmental standards, for example, the dynamics of airflow through a HEPA filter to achieve laminar airflow and the clean first air sweep of the DCA. It is also necessary to know how to achieve the air pressure differentials to produce the cascading effect from the buffer room out through the less clean ante area.

The use of barriers to interrupt the ingress of contaminants into the DCA must be understood, whether these are physical barriers such as walls or interruption barriers (e.g., removing supply items from a “dirty” cart, cleaning and disinfecting, transferring to a “clean” cart), or an interruption barrier as the washing of hands and the donning of clean garb before entering the buffer area.

Trainees must have a basic understanding of microbiology. They need to know that microorganisms are ubiquitous and, therefore, are present in the work environment, even in the DCA. They must know these organisms will multiply rapidly (doubling about every 20 minutes) when moisture, the proper temperature, and nutrients are present.

Compounding personnel should understand the principles of environmental evaluation (i.e., how to determine the effectiveness of the environmental controls used). This means knowing and selecting methods for detection of viable microorganisms in the environment, what the methods selected will detect, how samples should be gathered and incubated, proving that any viable microorganisms present will grow, and what the results signify, including when and if action is required.

Aseptic Technique

Typically, manipulations by compounding personnel are used in small-scale compounding of sterile preparations in the buffer area for low- and medium-risk preparations. Medium-risk preparations may require automated compounding devices for the addition of small-volume additives to total parenteral nutrition (TPN) solutions. Compounding personnel must set up such devices, connect fresh stock containers, fill the final preparation containers, and generally monitor the operation. High-risk preparations are particularly exposed to the environment and to compounding personnel.

Garb and Behavior

Because of the inherent shedding of viable and nonviable particles from the body of compounding personnel (as many as 1 million particles of 0.3 microns and larger per minute with average arm and upper-body movement from a sitting position), serious efforts must be made to control this shedding. Means used include garbing, designed to confine most of particulate discharge within the garb; planning movements while using aseptic technique to minimize losing particles from the body; and removing human beings as far as possible from the DCA. One of the advantages of using compounding aseptic isolators is the fact that the bodies of compounding personnel are physically separated from the DCA.

Before entering the buffer area, compounding personnel must remove outer garments, all cosmetics (because they shed flakes and particles), and all hand, wrist, and other visible jewelry or piercings that can interfere with the effectiveness of personal protective equipment (PPE) (e.g., fit of gloves and cuffs of sleeves). The wearing of artificial nails is prohibited while working in the sterile compounding environment. Natural nails must be kept neat and trimmed.

Personnel don the following PPE in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. Garbing activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers (e.g., beard covers in addition to hair bonnets), and face masks/eye shields. Eye shields are optional unless preparing hazardous drugs with a risk of spills or splashing. Thereafter, a hand-cleansing procedure must be performed by removing debris from under fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Hands and forearms are washed to the elbows for at least 30 seconds with soap and water while in the ante area. Hands and forearms to the elbows should be completely dried using either lint-free disposable towels or an electronic hand dryer.

After completion of hand washing, a nonshedding gown with sleeves that fit snugly around the wrists and enclosed at the neck is donned. Gowns designated for buffer area use must be worn, and they should be disposable. If reusable gowns are worn, they should be laundered appropriately for buffer area use. Once inside the buffer area and prior to donning sterile powder-free gloves, antiseptic hand cleansing must be performed using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations. Hands are allowed to dry thoroughly before donning sterile gloves.

Sterile gloves are the last item donned before compounding begins. Gloves become contaminated when they contact nonsterile surfaces during compounding activities. Disinfection of contaminated gloved hands may be accomplished by wiping or rubbing sterile 70% IPA to all contact surface areas of the gloves and letting the gloved hands dry thoroughly. Only use gloves that the manufacturer has tested for compatibility with alcohol disinfection. Routine application of sterile 70% IPA must occur throughout the compounding process and whenever nonsterile surfaces (e.g., vials, counter tops, chairs, carts) are touched. Gloves on hands must also be routinely inspected for holes, punctures, or

tears and replaced immediately if such are detected. Compounding personnel must be trained and evaluated in the avoidance of touching **critical sites**. When compounding personnel exit the compounding area during a work shift, the exterior gown may be removed and retained in the compounding area if not visibly soiled, to be re-donned during that same work shift only. However, shoe covers, hair and facial hair covers, face masks/eye shields, and gloves must be replaced with new ones before re-entering the DCA, and proper hand hygiene must be performed.¹⁷ The following lists some elements of good aseptic technique:

1. Practice good personal hygiene; be organized and calm.
2. Be healthy, without eczema or other skin rashes, and free from allergies or other conditions causing sneezing or coughing.
3. Put on garb properly, avoiding contaminating the outside of the clean/sterile gowns.
4. Replace garb or parts of garb that become contaminated while gowning or working.
5. Disinfect all interior surfaces of the LAFW (except the HEPA filter face) with sterile 70% IPA.
6. Disinfect gloves frequently while performing aseptic technique to maintain the aseptic condition of the outer surfaces.
7. Replace gloves with new sterile ones if they become punctured or torn.
8. Move with slow, smooth, gentle motions.
9. Do not talk unnecessarily.
10. Do not disrupt HEPA-filtered laminar airflow within the DCA.
11. Do not interpose arms or any other nonsterile objects above a critical site in BSC or behind a critical site in horizontal laminar airflow.
12. Do not spray or splash disinfectants where the liquid might enter a preparation container or reach other preparation contact sites.
13. Do not introduce any packages into the buffer area unless they have been adequately disinfected or sterilized externally.
14. Minimize in and out movement at the LAFW, BSC, or CAI.
15. Disinfect gloves with sterile 70% IPA after handling any package if the outside had uncertain sterility or surfaces such as switches of mixing pumps.
16. Cooperate with other compounding personnel and mutually assist in maintaining proper aseptic technique.
17. Pass through doorways, plastic curtains, or other passageways slowly and carefully to minimize the generation of potentially contaminating air currents.
18. Do not leave open vials, tanks, or other critical sites exposed to the environment during breaks or other delays in operation.
19. Inspect all supply items before using and the finished preparation after preparation for evidence of defects.
20. Remove used supply items and clean/disinfect work area as needed.

KEY POINT . . .

Competent personnel using good aseptic technique are the foundation of compounding sterile preparations made from manufacturers' sterile products.

. . . SO WHAT?

Ultimately, good sterile compounding comes down to excellent human resources management including the recruitment, training, monitoring, and coaching of employees.

21. Prepare and apply appropriate labels and complete documents away from the direct compounding area or, preferably, pass preparation outside so that a second person can perform the paperwork.
22. Remove used garb carefully to avoid distributing accumulated body contamination before exiting the gowning room.
23. Leave the HEPA filter blower operating at all times.

PACKAGING AND LABELING

The final container for a CSP needs to be sterile and maintain the sterility of the preparation to the BUD. It should also protect the final preparation from chemical degradation, especially if the preparation is light sensitive. The choice of package for a sterile preparation should take into account the use of the preparation. For example, ophthalmic medications need to be packaged for drops to be instilled in the eye. Irrigation solutions need to accommodate administration sets, if necessary, and ideally not be confused with IV drug administration containers. Plastic containers are preferred for most sterile medications to reduce cost and to prevent breakage, but a plastic container should not be used if the preparation is not compatible with plastic or if heat sterilization of the final preparation is needed.

Proper labeling is an important component of safe medication systems because it identifies the medication, quantity of medication, and BUD. If the preparation is patient-specific, it also associates the medication with the patient for whom it is intended and the dose that is prescribed. Labels may also include supplementary information to help ensure the dose is administered properly such as how to store the preparation, when to administer the dose, and how to prepare the dose for administration. Special techniques can be used to highlight important characteristics of drug names or doses to avoid confusion that might result from look-alike or sound-alike drug names or doses. Examples are bold letters, larger font, color, or capital letters (so-called *TALL MAN* lettering) for drug names or concentrations or doses. It is important not to include too much information on a label so that the user cannot or does not read the information. Specific requirements for labeling compounded sterile preparations often include the following:

- Name and amounts or concentrations of ingredients
- Total volume of the CSP
- BUD
- Appropriate route of administration
- Storage conditions (e.g., refrigerate, protect from light)
- Other information for safe use (e.g., cautionary statements, initials of responsible pharmacist, disposal instructions)

Patient-specific labeling may include additional information to ensure proper drug administration:

- Patient name and identification number
- Patient location
- Name and amount of drug(s) added and the name of the admixture solution
- Time and date of scheduled administration
- Time and date of preparation
- Administration instructions
- Initials of the persons who prepare and check the IV admixture

VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY

Two components of CSPs are essential—the accuracy of the content and sterility. Manufactured products cannot be used before these two factors are ensured. It is not possible to wait for the results of tests to measure content or sterility for compounded preparations because of the urgency of clinical need. Therefore, more indirect methods of quality assurance are required.

Measures of compounding accuracy are directed toward ensuring the content of the admixture matches what is ordered and printed on the label. This can be done for parenteral nutrition formulations by weighing an admixture. The expected weight of the final preparation can be calculated using specific gravity of the components. Deviations from the calculated weight would suggest that a wrong base solution or the wrong volume of one or more of the base solutions was used to compound the preparation. More commonly, the person preparing an admixture is asked to place the syringes and vial/ampuls used to compound the preparation on a tray with the final admixture for a pharmacist to check. These supplies are checked to verify the use of the proper component(s) and volume (based on syringes drawn to the amount used) for each admixture.

Newer workflow software and technology allows verification of admixture components and compounding remotely. These software programs utilize barcode verification of the components of the preparation as well as some form of picture, video, or gravimetric measurement for confirmation and visual inspection by the pharmacist. The systems can be programmed to require pharmacist verification prior to admixture as well as the final product.

STORAGE AND BEYOND-USE DATING

Two important considerations in ensuring the quality of pharmacy CSPs are the conditions under which the preparation is stored and the time that elapsed between compounding and administration. These are important because of both chemical stability and sterility considerations. Chemical stability issues can be determined from the package insert, a reliable reference such as *Extended Stability for Parenteral Drugs*²⁵ the *Handbook on Injectable Drugs*,¹⁹ or other published literature.

Sterility considerations are defined in USP Chapter <797>.¹⁷ In the absence of passing a sterility test, USP requires beyond-use dating of 48 hours at controlled room temperature, 14 days at cold temperature, and 45 days in solid frozen state at -20°C or colder for low-risk level CSPs. For medium-risk CSPs, the beyond-use dating is shorter: 30 hours at controlled room temperature, 9 days at cold temperature but still 45 days frozen. For high-risk preparations, beyond-use dating should not exceed 24 hours at controlled room temperature or 3 days at cold temperature and 45 days frozen unless sterility testing provides evidence to the contrary.

To protect the patient, the BUD should be provided on the label of the CSP.

HAZARDOUS DRUGS AS COMPOUNDED STERILE PREPARATIONS

With the creation of USP Chapter <800>, a new set of safe-handling requirements for HDs became enforceable. Previously, practitioners had to rely on the best practice documents such as the *ASHP Guidelines on Handling Hazardous Drugs*²⁶ and the National Institute of Occupational Safety and Health (NIOSH) Alert: *Preventing Occupational Exposures to Anti-neoplastic and Other Hazardous Drugs in Health Care Settings*.²⁷ Although these best practice documents were based on evidence-based practice, implementation was inconsistent in healthcare settings. USP Chapter <797> incorporated some of the recommendations from

ASHP and NIOSH; however, Chapter <800> supersedes and expands on the requirements of Chapter <797>. With Chapter <800>, the NIOSH list of HDs is made official and enforceable, the environmental controls required for safe handling are standardized, and PPE for handling HDs is clarified.

List of Hazardous Drugs

All healthcare entities must maintain a list of HDs that they handle, and this list must include, at a minimum, those items on the current NIOSH list²⁸ as well as any new drugs or dosage forms that are used. The NIOSH list contains three categories of HDs: *antineoplastic*, *non-antineoplastic*, and *reproductive risk* drugs. USP Chapter <800> requires full compliance only for handling of any **active pharmaceutical ingredient (API)** and antineoplastic HDs requiring manipulation. APIs are typically used for nonsterile compounding; however, antineoplastic HDs commonly require manipulation during sterile compounding, making knowledge of and compliance with the requirements of Chapter <800> essential for anyone performing sterile compounding.

Facilities and Engineering Controls

USP Chapter <800> expands on the facilities and engineering controls specified in Chapter <797> by adding the concept of containment to the primary and secondary engineering controls. HDs must be received and unpacked in a segregated area that is neutral or negative pressure to prevent contamination from any broken containers from spreading. After unpacking, HDs must be stored in a **negative-pressure room** with appropriate air changes, including refrigerated HDs. Because of this requirement, HD refrigerators are often placed inside the buffer area for HD compounding.

The compounding of HDs must be performed in a **containment primary engineering control (C-PEC)** that meets all of the requirements of a PEC but also must be exhausted externally to maintain a negative-pressure environment. The C-PEC must be placed in a **containment secondary engineering control (C-SEC)**. The C-SEC must be a physically separated room (with fixed walls), be externally vented, have an appropriate number of air changes per hour (ACPH), and must have negative pressure of 0.01 to 0.03 inches water column relative to other areas.¹⁸ The C-SEC can either be a buffer room with ISO Class 7 or better quality air and 30 ACPH, or a **containment segregated compounding area (C-SCA)** with unclassified air quality and 12 ACPH. Only low- and medium-risk HD CSPs may be compounded in a C-SCA, and they must be assigned BUDs based on Chapter <797> for CSPs compounded in an SCA.¹⁸ If the C-SEC is a buffer area with ISO Class 7 air quality, the anteroom for the C-SEC must also maintain ISO Class 7 air with 30 ACPH, but it must be positive pressure to prevent entry of particulates into the buffer room.

Personal Protective Equipment

The PPE required and appropriate use of it for HD compounding varies from PPE used for non-HD compounding with respect to permeation through the materials and the handling/disposal to prevent the spread of contamination. Appropriate PPE must be worn during receipt, storage, transport, compounding, administration, decontamination and cleaning, spill control, and disposal. PPE required for HD compounding includes:

- Double chemotherapy gloves (outer glove must be sterile)
- Gowns resistant to HDs handled and disposable
- Double shoe covers (the outer cover being removed when leaving the C-SEC)
- Appropriate eye protection
- Respirator when unpacking HDs not contained in plastic

All PPE used for HD compounding must be assumed to be contaminated with trace amounts of HD residue and should be disposed of appropriately. The outer chemotherapy glove should be removed before exiting the C-PEC and bagged for disposal to prevent the spread of HD residue through touch contamination.

Compounding and Administering

When compounding HDs, negative-pressure techniques should be used to minimize overpressurization of containers. When over-pressurized, HD vapors can escape from the container and contaminate the C-PEC, C-SEC, and personnel. **Closed-system drug-transfer devices (CSTDs)** can reduce contamination by mechanically preventing the release of these vapors and can compensate for poor negative pressure compounding technique. USP Chapter <800> requires that CSTDs must be used when administering HDs, when the dosage form and route allows.¹⁸ Because of the requirement for use of CSTDs during administration and the reduced risk of exposure when used, many compounders choose to use them during compounding although not required to do so.

Deactivating, Decontaminating, Cleaning, and Disinfecting

In addition to the disinfection required for non-HD compounding, all reusable equipment, and facilities used for HD compounding must also be deactivated, decontaminated, and cleaned. Deactivation refers to rendering the HD inactive or inert by chemically changing it, such as through oxidation. There is no universal deactivation agent, but sodium hypochlorite (bleach) and peroxide formulations have been studied.¹⁸ *Decontamination* refers to removing the HD residue from the surfaces, usually through transferring to another surface or vehicle (e.g., wipes), which is then disposed of as chemotherapy waste. *Cleaning* refers to the use of a germicidal detergent to remove any organic or inorganic materials.¹⁸ A complete procedure for HD compounding area cleaning will include all of these strategies to eliminate HD contamination.

MAINTAINING QUALITY AFTER THE PREPARATION LEAVES THE PHARMACY

Assurance of proper storage conditions can pose a challenge after the CSP leaves the pharmacy. Temperature limits can be exceeded during delivery to the patient or patient care area. Proper storage after the dose is received in the patient care area must also be ensured. Usually this means CSPs are stored in a refrigerator. To accomplish this, it may be desirable for the pharmacy to assume responsibility for delivery and storage of CSPs after they leave the pharmacy. If this is not possible, shorter beyond-use dating can be used.

Another challenge to maintaining quality after CSPs leave the pharmacy is the reuse of the preparation for a patient other than the one for whom the original preparation was compounded. Redispensing of CSPs may avoid waste but requires oversight by pharmacy to avoid administering doses that might be contaminated or after the BUD. USP requires that pharmacy have the sole authority for determining whether a CSP not administered as originally intended can be used for another patient.¹⁷ Some examples of considerations in making this decision include the following:

- CSP was maintained under continuous refrigeration
- CSP was protected from light
- No evidence of tampering
- Time remaining before originally assigned BUD and time

STANDARD OPERATING PROCEDURES

USP requires that the pharmacy has written and approved SOPs to ensure the quality of the environment and operator technique used to compound sterile preparations.¹⁷ There are specific parts to these SOPs that are recommended:

- Access to the buffer or clean area
- Decontamination of supplies in the anteroom area
- Storage of supplies not needed for scheduled operations
- Use of carts to transfer supplies and preparations
- Use of particle-generating objects (e.g., pencils, cardboard, paper)
- Traffic flow
- Policy for cosmetics and jewelry
- Procedures for hand washing
- Policy for food items
- Procedures for cleaning surfaces in the compounding environment
- Policy for maintaining ISO class 5 direct compounding area conditions
- Handling of supplies within the direct compounding area
- Inspection and final preparation checking procedures
- Removal of preparations and supplies from the DCA
- Environmental monitoring

Readers are referred to USP Chapter <797> for more detailed SOPs.¹⁷

KEY POINT . . .

In compounding most sterile preparations, final sterility and accuracy testing is not possible, so having excellent policies and procedures is mandatory and compounders must use them correctly each time for consistency and uniformity of CSPs.

. . . SO WHAT?

Ultimately, the most important thing is the outcome, not the policies and procedures that result in the outcome of sterile and accurate compounding.

However, it is not feasible to check every product developed, so consistent and uniform compliance with policies and procedures is used to ensure quality of sterile products.

COMPLIANCE WITH USP CHAPTER <797>

In the first quarter of 2015 (more than 7 years after revised USP Chapter <797> became official and enforceable), a national survey of 349 hospitals of various sizes and in various U.S. states showed that hospital pharmacies still have not made a lot of progress with the standards of this chapter.²⁹ Only 39% of respondents to this survey reported their pharmacy meets or exceeds all requirements of Chapter <797>. However, 46% said they meet most of the requirements of the chapter, and 7% said they meet some. Surprisingly, 4% stated that they have no plan for compliance, even after the recent tragedies and increased enforcement efforts.

Regulators are interested. Seventy-three percent of State Board of Pharmacy inspectors asked about compliance with USP Chapter <797>. Fifty-four percent of hospital pharmacies reported that they have a clean room that uses standard gypsum wall construction, 32% have a modular hardwall clean room, and only 9% utilize the open architecture room. Sixty-three percent of hospital pharmacies have an environmental monitoring plan in place. Forty-six percent of hospital pharmacies utilize CSTDs for compounding, which is

the highest percentage reported since the survey started. In light of the recent publication of USP Chapter <800>, this percentage is likely to increase.



SUMMARY

Centralized, pharmacy IV admixture programs are an evidence-based practice for minimizing the risks of patient harm with IV drug therapy. This system should be in place for compounding all IV medications for routine use in the health system. There are cases where the clinical needs of the patient are too critical for the time required for a dose to be compounded in a centralized, pharmacy IV admixture area and delivered to the bedside. In these instances, doses may need to be prepared extemporaneously in patient care areas, often by nonpharmacy personnel. In these situations, greater vigilance is needed to ensure the accuracy of calculations and technique used to prepare the dose. This may be done by having another caregiver double-check the drug identity and dose prepared. Alternatively and perhaps better, premixed, frozen, or point-of-care activated devices may be used to ensure accuracy and maintenance of sterility when a dose is needed quickly. In spite of the increased safety in preparing the dose, the pharmacist's double-check of the physician's order is often bypassed with these systems. Healthcare professionals need to work collaboratively in choosing the right system to optimize the benefits of parenteral therapy (see Chapter 16).

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CHAPTER REVIEW QUESTIONS

1. **What are the physiologic barriers the IV route of administration bypasses that creates a higher risk for preventable adverse medical events?**

- a. Gut, liver, skin
- b. Kidneys, pancreas
- c. Blood-brain barrier
- d. All of the above

Answer: a. Gut, liver, skin. The gut may break down medications before they are ever absorbed, or the drug may not even be absorbed through the gastrointestinal tract. The liver protects patients from many toxic doses of medications and can safeguard patients through the first-pass effect when medications are administered orally. The skin protects patients from infections that might be caused by pathogenic microorganisms in the environment, especially the hospital.

2. **Which of the following risk levels of compounding involves the use of components that are not sterile and may not be pyrogen-free?**

- a. Low risk
- b. Medium risk
- c. High risk
- d. None of the above

Answer: c. High risk. Low- and medium-risk compounding requires that all components are sterile and pyrogen-free. If any nonsterile or pyrogenic components are used in compounding, it is considered high risk.

3. **Which document contains the exact directions for the compounding of a batch preparation?**

- a. Batch control record
- b. Standard operating procedure (SOP)
- c. Master formula sheet
- d. None of the above

Answer: c. Master formula sheet. The master formula sheet provides exact directions on the standard compounding of the batch preparation

4. Which of the following areas requires air quality of at least ISO 7 or better for sterile compounding?

- a. DCA
- b. PEC
- c. C-PEC
- d. C-SEC
- e. None of the above

Answer: e. None of the above. The DCA, PEC, and C-PEC must all provide an ISO Class 5 or better air quality environment. The C-SEC for HD compounding may be a C-SCA, which is an unclassified air quality environment.

5. Which of the following types of compounding require a physically separate room?

- a. Immediate use
- b. Low risk
- c. Low risk, less than 12-hour BUD
- d. Medium risk
- e. Hazardous drug (HD)

Answer: e. Hazardous drug (HD). All HD compounding must be performed in a physically separated room from non-HD compounding. The room can be either a classified space or an unclassified C-SCA.

6. Which of the following components used for compounding would require full compliance with USP Chapter <800>?

- a. API of any drug
- b. Antineoplastic HDs in unit dose packaging to be crushed
- c. Non-antineoplastic HDs
- d. Reproductive risk HDs
- e. None of the above

Answer: b. Antineoplastic HDs in unit dose packaging to be crushed. API of any HD must follow USP Chapter <800>; non-antineoplastic HDs and reproductive risk HDs can be exempted from some of the requirements of USP Chapter <800> provided the facility completes an Assessment of Risk annually and provides alternative containment and risk reduction strategies.

7. Which of the following is likely to contribute the most microbial contamination to a sterile compounding work environment?

- a. Floors
- b. Walls
- c. Ceiling
- d. Personnel

Answer: d. Personnel. People generate more particles than any other source in a clean room.

8. Which of the following items of garb is NOT required for sterile, non-hazardous drug compounding?

- a. Goggles
- b. Gown
- c. Gloves
- d. Shoe covers

Answer: a. Goggles. Goggles are not required unless working with a hazardous or toxic substance.

9. Verification of compounded sterile preparations by a pharmacist is:

- a. Not necessary of technicians who are board certified.
- b. Acceptable if two technicians verify the preparation.
- c. Can be done remotely by a pharmacist using workflow technology.
- d. Requires a pharmacist to be physically present in the clean room.

Answer: c. Can be done remotely by a pharmacist using workflow technology. Workflow technology that includes video and component verification features enable a pharmacist to verify sterile preparations compounded by a pharmacy technician remotely.

10. Which of the following is considered a HD?

- a. Antineoplastics
- b. Some drugs that are not antineoplastics
- c. Drugs that pose a reproductive risk
- d. All of the above

Answer: d. All of the above. NIOSH defines three categories of HDs: antineoplastics, non-antineoplastics, and reproductive risk.

CHAPTER DISCUSSION QUESTIONS

- 1. Describe the risks inherent to high-risk compounding and why the standard BUD for these preparations is shorter.
- 2. Explain the reason for the different environmental controls for HD compounding compared to non-HD compound.
- 3. Why are double gloves and shoe covers needed for HD compounding, but double gowns are not required?
- 4. Describe how to justify the cost of SECs to an administrator.
- 5. How would you explain the need to remove all jewelry and cosmetics before donning sterile garb?
- 6. What additional facility needs are required in the pharmacy for compounding sterile preparations containing HDs?

Parenteral Therapy

Julie A. Patterson and David A. Holdford

LEARNING OBJECTIVES

After completing this chapter, readers should be able to:

1. Describe how parenteral drug therapy is delivered.
2. List the various devices utilized in administering parenteral therapy.
3. Explain the risks associated with parenteral therapy administration.
4. Discuss how to manage the hazards associated with administering parenteral therapies.
5. Define key terms used in parenteral therapy administration.
6. List the different administration routes of parenteral therapy and their characteristics.
7. Describe national and institutional standards that influence parenteral therapy administration.

KEY TERMS AND DEFINITIONS

- **Ampul:** A single-use container composed entirely of glass.
- **Cannula:** A tube-like needle or catheter used to infuse parenteral fluids and medications into the vascular system or other body spaces.
- **Electrolyte:** Dissolved ions that include sodium, potassium, chloride, calcium, phosphate, and others.
- **Epidural:** The space superior to the dura mater of the brain and spinal cord and inferior to the ligamentum flavum; outside the subarachnoid space where the cerebrospinal fluid flows.
- **Extravasation:** The inadvertent administration of vesicant medication or solution into the tissue surrounding an artery or vein. Extravasation is an adverse drug event.
- **Incompatibility:** Incapable of being mixed or used simultaneously without undergoing chemical or physical changes or producing undesirable effects. Undesirable effects might include loss of potency of active ingredients, formation of precipitates or toxic ingredients, color changes, etc.
- **Infiltration:** The inadvertent administration of non-vesicant medication or solution into the tissue surrounding an artery or vein. Infiltration is an adverse drug event, unless infiltration is intended (e.g., local anesthetic).
- **Intrathecal:** The space within the spinal canal.
- **Parenteral (or injectable):** Dosage form intended for injection through one or more layers of skin or other external boundary tissue, rather than through the alimentary (enteral) canal, so that the active substances they contain are administered directly into a blood vessel, organ, tissue, or lesion.
- **Sharps:** Objects in the healthcare setting that can be reasonably anticipated to penetrate the skin and to result in an exposure incident; including but not limited to needle devices, scalpels, lancets, broken glass, or broken capillary tubes.

- **Standard precautions:** Guidelines designed to protect workers with occupational exposure to blood borne pathogens. All blood and body fluids are treated as potentially infectious.
- **Total parenteral nutrition (TPN) or hyperalimentation:** The intravenous provision of total nutritional needs for a patient who is unable to take appropriate amounts of food enterally. Typical components include carbohydrates (e.g., dextrose), proteins (e.g., amino acids), and fats (e.g., oil emulsion) as well as electrolytes, vitamins, and trace elements.
- **Vehicle:** For most parenterals, sterile water for injection (USP) is the liquid in which active ingredients are dissolved, suspended, or emulsified. Other vehicles include ethanol and fixed, odorless, vegetable oils that are occasionally used to dissolve solutes that do not dissolve in water.
- **Vial:** A plastic or glass container with a rubber closure secured to its top by a metal ring.



INTRODUCTION

Particularly in institutional and home infusion settings, pharmacists often receive orders from physicians for drugs to be administered by a parenteral route. Because pharmacists must interpret and carry out these orders appropriately, it is their professional responsibility to understand what the physician intends and what risks are involved in the preparation and use of parenterals. Chapter 15 describes the compounding and quality control of sterile preparations. This chapter discusses how parenteral drug therapy is delivered, the risks associated with parenteral therapy, and how to avoid those risks. Pharmacists often receive questions from nurses and other caregivers who administer parenteral medications. Thus, pharmacists must be familiar with administration of parenteral drugs as well as preparation and dispensing.

PARENTERAL ROUTES OF ADMINISTRATION

Parenteral drug administration comprises a number of specific routes of administration, all of which deliver medications non-orally by a route that does not pass through the digestive tract. These routes have previously been described by Allen.¹ Parenteral routes of administration include:

- **Intravenous (IV)** — Administration can deliver large or small volumes of fluid into veins. This chapter is devoted primarily to the IV route because it is the most commonly used in the hospital setting and poses some of the greatest risks. Indeed, over 90% of hospitalized patients receive IV drugs, which account for nearly 80% of harmful or fatal parenteral medication errors.^{2,3} IV medication errors can be especially dangerous given the immediate onset and limited reversibility of IV medications as well as the narrow therapeutic index of many drugs delivered by this route.
- **Intramuscular (IM)** — IM injections are made into a muscle mass. The injection site limits the maximum volume that can be administered by the IM route. For example, a maximum of 2 mL and 5 mL can be injected into the deltoid of an adult's upper arm and gluteal medial muscle, respectively. Drug absorption by the IM route is less rapid than with IV administration but faster than with most other injectable routes. However, IM dosage forms can be formulated for delayed release by suspending the drug dose in an aqueous or oil-based vehicle.

- **Subcutaneous (Sub-Q)** — Sub-Q injections are given in the loose tissue beneath the skin, generally in the outer surface of the arm, abdomen, or thigh. Subcutaneous drug absorption is less rapid than with the IV and IM routes. Rarely, medications can be given by continuous subcutaneous infusion (a.k.a. hypodermoclysis).
- **Intradermal (ID)** — ID injections are given into the superficial layer of the skin between the epidermis and the dermis. The maximum volume that can be administered ID to an adult patient is 0.1 mL, and absorption is slow relative to other forms of injection. Intradermal administration is used for diagnostic skin tests (e.g., tuberculin) and a few vaccines (e.g., influenza, rabies). Drugs given IV, IM, Sub-Q, or ID may be in the dosage form of a solution, a suspension, or an emulsion.
- **Intra-arterial (IA)** — IA injections are given into an artery. This route is not used often, and accidental administration by this route often contributes to serious complications. A drug administered IA can go directly to a targeted area, which may be an organ (e.g., radiopaque dye for an arteriogram) or limb (e.g., local anesthetic for a regional block).
- **Central nervous system routes** — They include injections into the spinal column including the intraspinal, **epidural**, and intrathecal routes. These routes are commonly used for analgesia and pain management purposes. Intracranial and intraventricular injections are given directly into the brain.
- **Musculoskeletal routes** — They include intrasynovial injections into a joint fluid area, intra-articular injections into the cavity of a joint, and intraosseous injections into the bone matrix.

Other uncommon routes of injectable parenteral administration include intracardiac injections directly into a chamber of the heart and intraperitoneal injections.

Advantages of Parenteral Therapy

Parenteral therapy can be advantageous in a number of clinical situations. Rapid physiological responses can be achieved with parenteral administration, an important consideration in emergent clinical conditions such as cardiac arrest or volemic shock. Parenteral therapy also provides an effective and rapid way of correcting serious fluid and **electrolyte** imbalances to minimize the complications associated with these imbalances. Conversely, parenteral dosage forms may provide opportunities for prolonged drug action, as is the case with long-acting steroids injected into joints or long-acting penicillins given by deep intramuscular injection. Long-acting and provider-administered treatments may be desirable to decrease medication regimen complexity or when patient nonadherence is likely and associated with treatment failure or adverse outcomes.

Parenteral administration can also be used when medication or clinical characteristics prevent drug administration by other routes. Patients who are nauseated, unconscious, or unable to take food by mouth or tube feeding can be supplied medication parenterally. Parenteral routes of administration are also required for drugs that are not effective orally due to barriers in the absorption or metabolism processes associated with oral delivery. Finally, parenteral administration can result in local effects for drugs as when local anesthetics or anti-inflammatory drugs are injected at the affected site.

KEY POINT . . .

Parenterals are made in a variety of sizes and containers for a variety of uses, but all are injected into or beneath the skin.

. . . SO WHAT?

Once a chemical penetrates the skin barrier, the potential for a negative patient health outcome increases greatly.

Disadvantages and Risks of Parenteral Therapy

Regardless of the parenteral route of administration, disadvantages and potential hazards exist.⁴ Trained personnel must administer the dosage forms, which typically require more nursing time than those administered by other routes. Parenteral administration requires strict adherence to aseptic procedures and can cause some pain on injection. Once a drug has been given parenterally, it becomes more difficult to reverse the physiological effects. Finally, because of manufacturing and packaging requirements, parenteral dosage forms are more expensive than similar drugs given orally.

Infusion of a parenteral product or compounded preparation into a vein can lead to phlebitis (inflammation of the vein) or thrombophlebitis (inflammation and a clot in a vein). An early sign of phlebitis is tenderness at the insertion site of the IV needle or **cannula**. As phlebitis worsens, the vein becomes red, warm, and painful with edema and stiffness. In the latter stages of phlebitis, the vein appears as a palpable, tender red cord.⁴ Infusion phlebitis can last for a week or more, can induce fever, and predisposes the patient to sepsis. Factors associated with infusion phlebitis include the type of needle used, duration of IV therapy, irritant nature of the drugs, pH of the infusion, osmolality of the IV fluid, location of the IV site, decreased blood flow, and possibly the presence of particulate matter in the infusion.⁴

Infiltration, extravasation, or the accidental intra-arterial injection of some drugs can cause necrosis resulting in tissue damage and potential loss of a limb. Caustic or vesicant drugs (e.g., chemotherapy) or vasoconstricting drugs are most often implicated in these injuries.

Particulate matter (mobile, undissolved, and unintended particles other than gas bubbles) has been reported in a variety of manufactured and compounded parenterals, including large and small volume parenterals, dry-filled and lyophilized drugs, **total parenteral nutrition (TPN)**, and others. Excessive particulate matter infused intravascularly may clog capillary beds, contribute to phlebitis, and cause formation of granulomas or foreign body reactions. The United States Pharmacopeia (USP) has a monograph that requires manufacturers of parenteral products to limit the particulate load in their products (**Table 16-1**).⁵ Compounders of parenteral preparations can contribute to particulate load by any of the following errors:

- Failure to screen for incompatibilities that form precipitates (e.g., calcium phosphate complexes in TPN)⁶
- Failure to dissolve solutes that have precipitated (e.g., mannitol)
- Failure to filter out glass particles from opened ampuls
- Failure to fully dissolve dry powders or lyophilized powders (e.g., antibiotics)
- Introduction of ambient particles in the compounding process

TABLE 16-1.

USP Chapter <788> Particulate Matter in Injections

(light obscuration particle count test compliance*)

Large volume parenterals (>100 mL)	Average particle count does not exceed 25 per mL equal to or greater than 10 microns.	Average particle count does not exceed 3 per mL equal to or greater than 25 microns.
Small volume parenterals (<100 mL)	Average particle count does not exceed 6000 per container equal to or greater than 10 microns.	Average particle count does not exceed 600 per container equal to or greater than 25 microns.

Source: United States Pharmacopeia. <788> Particulate Matter in Injections. USP. 2011; 34:326-8.

*The light obscuration test uses suitable apparatus based on the principle of light blockage that allows for an automatic determination of the size of particles and the number of particles according to size. When the light obscuration test method cannot be used for a parenteral product because of its particular physical characteristics (e.g., emulsions, colloids, liposomals), the microscopic particle count test may be suitable.

Because of the hazards of particulate matter in compounded sterile preparations (CSPs), pharmacists checking CSPs should view the finished preparation against light and dark backgrounds to detect visible particles or cloudiness. Precipitates can form after the CSP leaves the pharmacy (e.g., when two incompatible drugs are mixed in IV tubing); therefore, some hospitals have a policy of filtering some or all IV fluids with a 0.22-, 0.45-, or 5-micron filter just before the fluids enter the administration cannula. The 0.22- and 0.45-micron filters have the disadvantages of slowing the rate of IV administration and more frequent filter blockage. This is not just inconvenient but also requires more frequent manipulation of the IV line. When IV pumps are used, consideration should be given to the pounds per square inch pressure rating of the filter.⁷

Infection, the presence and growth of a pathologic microorganism, is a less frequent but potentially more serious hazard of parenteral therapy and especially for IV therapy and injections into sites in joints, the eye, and central nervous system. Infections can be life-threatening in immunocompromised patients. IV infections may be infusate-related, catheter-related, or administration delivery system-related. The hazards of incorrectly compounded and contaminated IV solutions are discussed in Chapter 15.

KEY POINT...

Although parenteral therapy offers advantages such as rapid onset of drug action and more reliable drug levels, medication prescribers must weigh those advantages against inherent parenteral disadvantages of pain on injection, phlebitis, extravasation, infiltration, or infection.

...SO WHAT?

It is easy to take for granted the benefits of parenteral administration of medications and fluids. However, one must always be aware of the potential complications and the severity of errors made during preparation or administration.

PARENTERAL DRUG PREPARATION AND DISPENSING

Parenteral drugs are used for a variety of diagnostic, therapeutic, and palliative indications.¹ Based on the indication and information about the patient, the prescriber develops a prescription (or medication order) for a parenteral drug. Physicians' orders require a pharmacist's interpretation for correct compounding and dispensing. Pharmacists should know the patient's age, weight, diagnoses, and allergies to fill a parenteral drug order correctly. The medication order may not give the pharmacist all the information needed to prepare doses. For example, if the order reads "ampicillin IV 1 gram every 8 hours," the pharmacist usually decides whether the dose should be given intermittently or continuously; what the diluent will be; what the concentration of ampicillin in the diluent will be; what the hours of administration will be; the time over which the dose should be infused; and how many doses to prepare. The pharmacist must determine whether the dose is in an appropriate range for the patient, whether there might be an allergic reaction, and what incompatibilities to anticipate with other drugs given by the same route. Some of these pharmacist's decisions can be standardized within an institution (e.g., which diluent, what concentration, hours of administration), but other decisions are patient-specific (e.g., dose range, allergy history, incompatibilities).

Parenteral drugs come in a variety of containers and sizes, reflecting the diverse purposes of parenteral products including fluid and electrolyte replacement, nutrition, and as a **vehicle** for a prescribed drug. Examples of common categories of parenteral products include:

- Antineoplastic therapy (i.e., cancer chemotherapy)
- Biologic therapy (e.g., active and passive immunizations, allergen extracts, monoclonal antibodies)
- Diagnostic agents (e.g., contrast media, skin tests)
- Emergency treatments (e.g., autonomic drugs, antihypertensives)
- IV sedation (e.g., anxiolytics)
- Parenteral solutions (e.g., fluids and electrolytes)
- Parenteral drug therapy (e.g., antibiotics, insulin)
- Parenteral nutrition (e.g., TPN)
- Patient-controlled analgesia
- Radiopharmaceuticals
- Transfusions (i.e., blood, blood components)

Manufacturers may package parenteral drugs in **ampuls**, glass or plastic **vials**, prefilled syringes, cartridges, glass or plastic bottles, or plastic bags. Injections are commonly aqueous solutions of a drug but may also be colloidal dispersions, emulsions, or suspensions. Parenteral drugs often require pharmacist preparation to dilute drugs packaged in concentrated form to an appropriate concentration or volume. The final parenteral drug product may be delivered for administration in a syringe, small volume parenteral (SVP) container, or large volume parenteral (LVP) container. SVP containers may contain a single dose or multiple doses of a drug in a volume no greater than 100 mL. An example of a SVP is an IV piggy-back container (e.g., minibags or minibottles in 50 mL or 100 mL sizes) that carries a diluent for the active drug. LVPs are manufactured in bags or bottles up to 1000 mL. Common container sizes are 150 mL, 250 mL, 500 mL, and 1000 mL. LVPs typically contain fluids (e.g., sodium chloride 0.9%), nutrients (e.g., dextrose), and electrolytes (e.g., sodium, potassium chloride), or plasma volume expanders (e.g., albumin).

Parenteral containers, syringes, needles, and IV administration set-ups must be handled with aseptic technique and **standard precautions**. An in-depth discussion of aseptic technique is presented in Chapter 15. Personnel using a syringe and needle to withdraw a drug from a vial must use proper technique to avoid shearing off a small piece of the rubber stopper into the vial (*coring*). To reduce the likelihood of coring, the opening of the needle tip should be inserted into the stopper at a 45–60° angle. That angle should be gradually increased during needle insertion such that the needle is at a 90° angle as the slanted portion of the needle tip (the bevel) passes through the stopper. The use of extra-large needles to penetrate vials' rubber closures increases the chance of coring, so the smallest gauge (diameter) needles appropriate for the task should be used.⁸ Notably, gauge size decreases as diameter increases; an 18-gauge needle has a larger diameter than a 24-gauge needle.

An appropriate syringe size is also essential to proper preparation. When using an ampul in the preparation of a parenteral product, care must be taken when breaking open the ampul neck to avoid contaminating the drug product with glass particles. ASHP recommends the use of a 5-micron filter straw or filter needle to minimize particulate contamination when withdrawing contents of ampuls.⁹

KEY POINT . . .

Injectable parenterals are made in a variety of sizes and containers for numerous uses, but all are injected into or beneath the skin.

. . . SO WHAT?

Once a chemical penetrates the skin barrier, the potential for a negative patient health outcome increases greatly.

PARENTERAL MEDICATION ADMINISTRATION

To prevent infection, nurses and others who administer parenteral medications must adhere strictly to hand hygiene before beginning administration.¹⁰

Sites of Administration

Site selection for vascular access must include assessment of a patient's condition, age, diagnosis, vascular condition, history of previous access devices, and type and duration of therapy. The artery or vein must accommodate the size and length of the catheter required for the prescribed therapy (**Table 16-2**).¹¹ Vascular access may be peripheral in nature (e.g., in the hand, forearm, or antecubital fossa) or central (e.g., into the right atrium).

Methods of Administration

Personnel administering parenterals must have a thorough knowledge of the components of administration devices. The simplest device is a sterile syringe with a sterile needle attached. With the right size syringe and the right gauge (diameter) and length of needle, this set-up can be used for ID, Sub-Q, IM, or IV drug administration. The Centers for Disease Control and Prevention (CDC)¹² and the Immunization Action Coalition¹³ maintain recommendations for needle gauge and length based on injection site, age, and body mass.

Infusions are usually administered with an IV set. IV sets are comprised of a number of components, which may include, but are not limited to, a drip chamber and tubing through which the IV fluid travels, a clamp used to control the rate of infusion, and an injection port into which other medications or fluids can be injected into the infusion. The proximal end of the IV set is attached to the fluid container, commonly an IV bag. The distal end is inserted into an IV needle (e.g., “butterfly” needle) or an IV catheter.

The CDC's *2011 Guidelines for the Prevention of Intravascular Catheter-Related Infections* provides recommendations for the frequency with which to replace administration sets to retain sterility and patency.¹⁴ Specifically, the CDC recommends that primary and secondary sets, as well as add-on devices which are continuously used, should be replaced no more frequently than at 96-hour intervals but at least every 7 days. An exception to this recommendation is made for tubing to administer blood, blood products, or fat emulsions, which should be replaced within 24 hours of initiating the infusion. Additionally, tubing used to administer propofol must be replaced every 6 or 12 hours when the vial is changed. Due to a lack of high-quality evidence, no recommendations could be made regarding replacement intervals for intermittently used administration sets or needles to access implantable ports.

Depending on the therapy, infusions can be administered on a continuous basis at a prescribed rate of administration (**Figure 16-1**) or intermittently (**Figure 16-2**). *Continuous infusions* may be given at a steady rate measured in one of several units including mL per hour, mg per hour, mcg per kg per hour, and drops per minute, among others. Continuous infusions may also be adjusted, or titrated, periodically based on patient parameters such

KEY POINT . . .

There are many routes of parenteral drug administration, and all have special purposes; all require careful attention to institutional systems and procedures to avoid harm to patients.

. . . SO WHAT?

Many different issues are involved in choosing one route over another. Pharmacists should understand all of these issues in order to help influence their appropriate use.

TABLE 16-2.
Typical Infusion Access^{11,15-20}

Site Name	Common Locations	Clinical Considerations
PERIPHERAL ACCESS		
Peripheral, short	Adults: veins of the upper extremities. Neonates and pediatric patients: Additional sites include veins of the upper and lower extremities and of the scalp in neonates.	Used for temporary venous access. CDC recommends replacing every 72–96 hours. May be used for hydration, transfusions of blood or blood components, and drugs with moderate pH values (5 to 9) and a low osmolarity (<500 mOsm). Parenteral nutrition may be administered with an osmolarity up to 900 mOsm/L.
Peripheral, midline	Adults: Routinely in the antecubital fossa region; may consider the basilic, median cubital, cephalic, and brachial veins. Neonates and pediatric patients: Additional sites include veins of the head, neck, and lower extremities.	Appropriate for IV therapy lasting 7–30 days. May be used for hydrating solutions and drugs with moderate pH values (5 to 9) and a low osmolarity (<500 mOsm) (e.g., heparin, cephalosporins). Avoid vesicants and irritating drugs (e.g., dopamine, chemotherapy). Requires routine flushing. Parenteral nutrition may be administered with an osmolarity up to 900 mOsm/L.
Arterial	Adults: Consider radial, brachial, and femoral arteries. Neonates and pediatric patients: Additional sites include radial, post tibial and dorsalis pedalis.	Assessment of distal arterial perfusion should be conducted prior to insertion.
CENTRAL ACCESS		
Peripherally inserted central catheter line	Adults: Routinely antecubital fossa region. Consider the basilica, brachial, or cephalic veins. Neonates and pediatric patients: Additional sites include the head, neck, and lower extremities.	Length depends on anatomical measurements to ensure catheter tip placement to the junction of the superior vena cava and right atrium. Appropriate for IV therapy lasting weeks to months and up to 1 year. Can be used for antineoplastics, irritants, parenteral nutrition, and medications with pH values <5 or >9 or osmolarity > 600 mOsm.
Non-tunneled and tunneled catheter and implanted ports	Site selection should be determined per manufacturer’s labeled use(s) and directions for device insertion.	

CDC: Centers for Disease Control and Prevention; IV: intravenous.

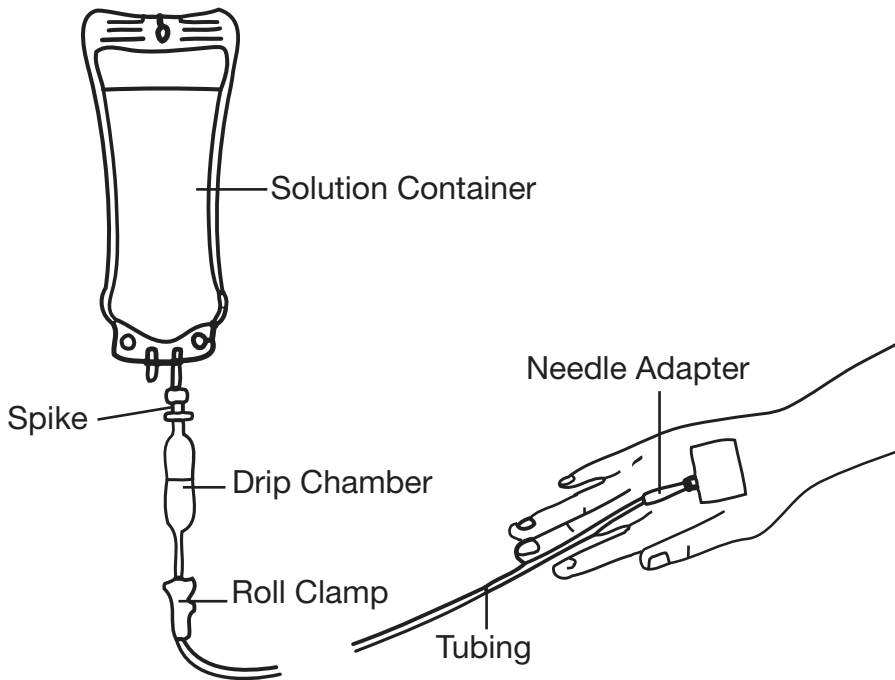


FIGURE 16-1. Set-up for continuous IV infusion.

Source: Reprinted with permission from Baxter Healthcare.

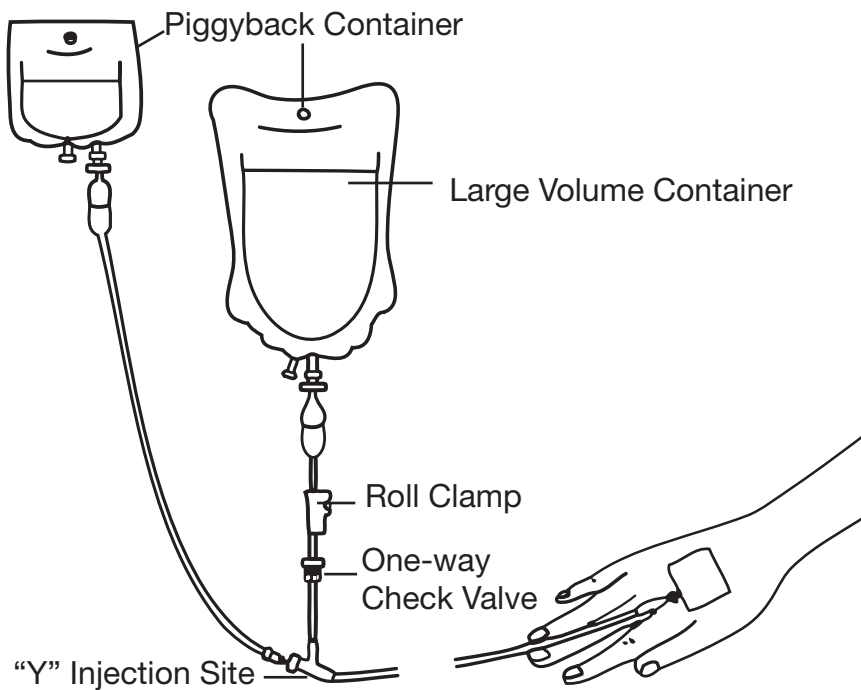


FIGURE 16-2. Set-up for intermittent IV infusion.

Source: Reprinted with permission from Baxter Healthcare.

as blood pressure, heart rate, and blood glucose. In 2016, the American Society of Health-System Pharmacists (ASHP), in partnership with the U.S. Food and Drug Administration (FDA), began an effort to develop and implement national standardized concentrations for continuous IV medications as an error-reducing strategy.²¹ Medications commonly administered continuously or continuously with titrations include regular insulin, opioids, benzodiazepines, and heparin.²¹

Intermittent IV therapy is administered at prescribed intervals with periods of infusion cessation between doses.²² The simplest intermittent therapy method is IV push. In IV push administration, the medication dose is prepared by drawing the drug solution into a syringe. The needle of the syringe is inserted into the infusion port in the IV set, and the caregiver applies pressure (“pushes”) as a bolus dose into the IV line. The caregiver then pushes a compatible IV solution, often normal saline, to flush the line and ensure that the entire drug dose flows through the IV tubing.²³ Providers must take care to administer the IV push medications over the timeframe specified in the medication labeling (e.g., 3 to 5 minutes) to avoid speed shock, a systemic reaction to medication administered too quickly.⁴ Medications that are commonly administered by IV push include antiemetics and proton pump inhibitors. The piggyback method of intermittent therapy differs from IV push in that the drug solution is contained in a smaller, secondary container (e.g., minibag, minibottle) rather than a syringe. The IV line from the piggyback container is connected into the primary IV line using a “Y site,” and the medication is administered alongside the primary IV solution.²⁴ IV piggyback dosing is typically used to deliver doses of antibiotics.

Intermittent IV infusions may also be administered by syringe pumps or burette sets. Syringe pumps deliver measured IV bolus doses by slowly injecting the contents of a syringe into a Y-site in a primary IV line. A burette set consists of a calibrated chamber and IV tubing that is attached to the primary IV set. Burette sets are commonly used to deliver smaller medication doses for pediatric patients. However, burettes are open containers that must admit air to administer their contents, and this venting may increase the risk of central line-associated blood infections.²⁵

Infusion Pumps

Flow-control devices known as infusion pumps were introduced in the 1970s to make infusion of critical drugs and fluids more accurate and uniform. These pumps, which accurately measure volume and flow rate, use one of several methods to apply pressure to the tubing and deliver the fluids. *Peristaltic pumps* move fluids through the IV tubing by intermittently squeezing the tube, often with a circular roller. This type of pump is generally used for parenteral nutrition and dialysis.²⁶ In *syringe pumps*, fluid is held in the reservoir of a syringe; a piston drives the syringe plunger forward to push the required volume of fluid through the IV tubing at a controlled rate.²⁷ Syringe pumps are limited in volume, generally to 60 to 100 mL. They are often used to deliver small volume parenteral therapy, high-potency drugs, chemotherapy, and pediatric dosages due to their ability to precisely and accurately administer small medication volumes.^{28,29} In *piston-cylinder pumps*, solutions are pushed through disposable cassettes using two cycles of high pressure to first pump fluid into the cassette chamber and then pump the volume through the IV tubing.³⁰

Elastomeric chambers are nonelectric medication pumps that consist of an expandable balloon-like chamber or fluid reservoir within a hard cylinder or shell. A flow-restrictor regulates the rate of administration by controlling the pressure exerted on the chamber by the elastic walls. Elastomeric chambers are commonly used for infusions of antibiotics, chemotherapy, or pain medications in outpatient or in-home settings.²⁶ Although their portability and simplicity are advantageous, elastomeric chambers have important disadvantages. The infusion rate when using elastomeric chambers can be impacted by temperature, solution viscosity, catheter size, fill volume, and pump height.³¹ Additionally, as nonelectric devices,

they lack many of the safety features of electric pumps, including rate and dose indicators as well as alarms. The type of infusion pump should suit the patient as to age, condition, prescribed infusion therapy, type of vascular access device, and healthcare setting.³²

Special purpose infusion devices include implantable pumps and patient-controlled analgesia pumps. *Implantable pumps* have a catheter surgically placed into a blood vessel, body cavity, or organ; the catheter is attached to a reservoir surgically implanted under the skin. The reservoir has a pumping mechanism. Implantable pumps are used to provide long-term injectable access, including **intrathecal** analgesia³³ and chemotherapy.³⁴ To limit contamination of implantable pumps, caregivers must use aseptic technique (i.e., hand hygiene, sterile gloves, masks) and small, non-coring needles when adding fluids to the pump.³⁵

Patient-controlled analgesia (PCA) is a process by which patients can determine the timing and quantity of pain medication they receive. PCA is most commonly administered by a specially designed IV pump. The pump is programmed so that a bolus dose of the analgesic is administered when the patient pushes a button. “Lockout” intervals may be programmed into the PCA pump to specify the amount of time (e.g., 10 minutes) that must elapse between bolus doses. The American Pain Society states that PCA use is appropriate in patients who will require analgesia for more than a few hours and have adequate cognitive function to understand the device and its safety limitations.³⁶ Meta-analysis results suggest that patients receiving PCAs for pain had lower pain scores and higher satisfaction than patients given non-patient controlled analgesia.³⁷ The American Pain Society recommends against the use of routine basal infusion of opioids with a PCA in opioid-naïve patients.³⁶ Evidence suggests that basal infusions offer no analgesia benefit over bolus dosing while increasing risks of nausea, vomiting, and respiratory depression.³

Smart Pumps

Electronic infusion pumps generally have a number of safety features including anti-free-flow mechanisms, dose-error reduction systems, and audible alarms.³² Although these safety features improve the accuracy and continuity of IV infusions, they do not prevent medication errors associated with incorrect IV pump programming.³⁸ To improve the safety of IV pumps, a new generation of infusion pumps called smart pumps has been introduced. Smart pumps are infusion pumps that incorporate software programs known as drug libraries to intercept potentially serious programming errors before they happen and alert providers.³⁹ Smart pumps have been linked to reduced adverse drug event rates and practice improvements in many, but not all, studies.^{39,40} The Institute for Safe Medication Practices (ISMP) and ASHP both recommend the use of programmable infusion pumps with dose error-reduction software for the infusion of high-alert IV medications.^{3,41}

Smart pump software contains facility-specific medication libraries with profiles that specify the infusion requirements for different patient types and care areas such as pediatric, adult, obstetrics, oncology, anesthesia, intensive care units, and post-anesthesia care units. Each profile contains hospital-defined drug infusion parameters such as acceptable concentrations, infusion rates, dosing units, maximum and minimum loading and maintenance doses, and bolus limits for 60 or more medications.⁴²

When a caregiver programs administration parameters for an infusion, smart pumps check the programmed settings against the hospital’s guidelines for specific drugs and patient groups and alert the caregiver if those settings are outside of recommended parameters.⁴³ Smart pump alerts may include clinical advisories offering the practitioner relevant information for drug administration; soft stops to alert a user that a dose is outside of the anticipated range; and hard stops that require the user to reprogram the dose to an acceptable range before infusion administration.⁴³ Soft stops have been shown to be less

effective than hard stops due to alert fatigue and high override rates.³³ Smart pumps record data about all such alerts, overrides, and edits, thus providing valuable continuous quality improvement information.⁴³ As of 2012, 77% of U.S. hospitals reported use of smart pumps, including 96% of hospitals with at least 600 beds.⁴⁴

Medication-Specific Considerations for Infusion Pumps

Because chemotherapy medications are often strong vesicants, chemotherapy infusions carry an increased risk of extravasation. Accordingly, the ISMP recommends that small volume vesicant infusions be infused by gravity and not by an infusion or syringe pump.⁴¹ Other common vesicants include hypertonic saline, phenytoin, vancomycin, and vasopressors.¹⁵ IV insulin infusions are commonly used in inpatient settings, particularly for critical care, labor and delivery, and perioperative patients. Insulin infusions are rapidly effective and easily titrated but also convey an increased risk for hypoglycemia. Validated, computerized protocols; hospital-wide standardized insulin infusion concentrations; and smart pumps with alarms to alert providers to check blood glucose levels and adjust infusion rates may improve outcomes in patients with insulin infusions.^{45,46}

KEY POINT ...

Although nurses administer most IV medications, including those given by infusion pump, pharmacists must play a role in the selection, policy-making, procedure development, drug libraries, and medication error monitoring associated with IV infusion devices.

... SO WHAT?

Pharmacists do not need to administer IV medications to influence their use. They can influence by understanding best practices, monitoring processes and outcomes associated with administration, and guiding the policies and procedures used within the institution.

DISPOSAL OF PARENTERAL MEDICATIONS

All blood-contaminated and sharp items including needles, surgical blades, and syringes must be discarded into nonpermeable, puncture-resistant, tamper-proof biohazard containers (i.e., sharps containers). **Sharps** must not be recapped, broken, or bent. Sharps containers must be replaced before they are full to avoid disposal-related injuries. All biohazardous materials, wastes, and drugs must be discarded in the appropriate containers and disposed of according to local, state, and federal regulations.⁴⁷

DOCUMENTATION OF PARENTERAL MEDICATION ADMINISTRATION

Nurses and others who administer drugs must provide complete and accurate documentation regarding infusion therapy and vascular access in the patient's permanent medical record. Documentation should include at least the following⁴⁸:

- Patient, caregiver, or legally authorized representative's participation in and validated understanding of therapy and care procedures.
- Type, brand, length, and size of vascular access device.
- Date and time of insertion, number and location of attempts, type of catheter stabilization and dressing, patient's response to the insertion, and identification of the person inserting the device.
- Identification of the insertion site by anatomical descriptors, landmarks, or appropriately marked drawings.

- Infusion site condition and appearance using standard assessment scales for phlebitis, infiltration, and extravasation.

PARENTERAL MEDICATION SAFETY

Evidence from numerous studies suggests that 50–60% of IV administrations have at least one clinical error.^{49–51} Even after controlling for unit, day of the week, and nurse staffing factors, injectable medications in one study were 3.3 times more likely than oral drugs to result in medication errors.⁵² Parenteral medication errors may also be more dangerous to patients. As mentioned in Chapter 15, the USP reported that “the intravenous route of administration often results in the most serious medication error outcomes” based on reports submitted to USP’s MEDMARXSM.⁵³ Specifically, parenteral medication errors were nearly three times as likely to cause harm or death (3%) compared with other errors reported to MEDMARXSM (1.2%).⁵³ The therapeutic categories most commonly associated with harmful or fatal parenteral medication errors were insulin, opioid analgesics, and blood coagulation modifiers—all high-alert medications.³

The majority of errors associated with IV medication use occur in the administration process, although errors in the preparation process are also common. Errors of omission, including omitted labels or incomplete labels lacking hand time and/or expiration dates, are common during IV preparation.^{49,54} Frequently cited IV administration errors include rate changes and incompatibilities.^{50,55} Bolus administrations have been associated with higher error rates and higher serious error rates than infusions^{50,54}; all of the IV bolus-related errors in one study were attributed to an incorrect rate of administration.⁵⁰ Recognizing the increased risks associated with IV push administration, the ISMP recommends that the pharmacy provides adult IV push medications to nursing in a ready-to-administer form.⁴¹ Appropriately labeling syringes and IV bags may also reduce medication administration errors at the bedside. Safety initiatives should also emphasize the potential for smart pumps to reduce medication errors. Schnock et al. reported that in 10% of observed infusions, smart pumps were either bypassed altogether or the available drug library was bypassed, typically during the administration of maintenance fluids.⁴⁹

It is important to recognize that simply having competent healthcare practitioners cannot eliminate IV medication errors. A complex array of human factors and system weaknesses contribute to errors, and safe medication practices are a combination of both interdisciplinary efforts of many individuals and reliable systems.⁵⁶ If the procedural rules cannot be followed because of system issues, healthcare givers have a duty to report the problem so it can be remedied.⁵⁶

With the systems approach in mind, a multidisciplinary summit meeting stated optimum IV system characteristics (**Table 16-3**). Another multidisciplinary group looked specifically at the safety of IV drug delivery systems.⁵⁷ **Table 16-4** summarizes some of the benefits and problems associated with each delivery system that this group identified. Note that centralized pharmacy admixture programs rank fourth out of five IV drug delivery systems, being safer only than when a nurse or direct caregiver can admix doses on the floor. Commercially manufactured, ready-to-use products were viewed as the safest in terms of potential and actual risk of harm (e.g., administration of the wrong medication, infections) to patients.

Pediatric patients require extra precautions in healthcare institutions, including in the administration of parenteral therapy. ISMP offers a number of best practices recommendations to minimize IV medication risk for pediatric patients, including⁵⁸:

TABLE 16-3.
Priority IV Medication Safety Practices

Step in Medication-Use Process	Priority IV Medication Safety Practices
Formulary management and medication-use policy	<ul style="list-style-type: none">■ Implement standardized infusion concentrations (dose, rate, units) based on local and national practices that are appropriate for most practice settings and allow exceptions, if needed■ Use commercially available ready-to-administer IV medications if available (except parenteral nutrient solutions)■ Limit available concentrations of parenteral medications on the formulary■ Implement hospital-wide standardized processes for high-alert medications■ Prohibit use of patients' own parenteral medications or establish strict criteria for exceptions■ Establish comprehensive IV medication administration policies, with standardized administration times, upper and lower dosage limits, and administration rates (especially for IV push and adjusted medications); policies for special patient populations; and policies that specify any required monitoring, special equipment, or unique competencies for administration■ Establish communication procedures for product shortages, recalls, and safety advisories, including recommendations for alternative agents
Prescribing and ordering	<ul style="list-style-type: none">■ Use standardized IV medication orders (paper or electronic format)■ Prescribe standardized infusion diluents, concentrations, and units (preferably commercially available products)■ Limit use of nonstandardized infusions to clinical indications in which benefits outweigh potential risks■ Use hospital-wide standardized dosing protocols for emergency drugs and high-alert medications (e.g., heparin, insulin)■ Differentiate look-alike medications when ordering■ Use clinical decision support at the point-of-care (e.g., drug allergy and drug interaction alerts, dosage calculators)
Storage	<ul style="list-style-type: none">■ Stock commercially available ready-to-administer infusions for emergency use in patient care areas where possible■ Differentiate look-alike medications, including separate storage locations■ Prohibit or impose tight security precautions on stocking concentrated injectable products and more than one concentration of an IV medication on patient care units■ Designate storage locations of authorized medications on patient care units (i.e., minimize variability in storage locations)■ Adopt ISMP guidelines on interdisciplinary safe use of automated dispensing cabinets

TABLE 16-3. (CONT'D)**Priority IV Medication Safety Practices**

Step in Medication-Use Process	Priority IV Medication Safety Practices
Preparation and dispensing	<ul style="list-style-type: none"> ■ Dispense IV medications and admixtures in ready-to-administer form (i.e., a form that requires no manipulation prior to administration) ■ Standardize process for compounding sterile preparations, with procedures to minimize unnecessary interruptions and distractions, trace and verify the accuracy of compounding, and provide for pharmacist checking of compounding accuracy ■ Label IV admixtures using standard format with information needed by staff who will administer admixtures prominently displayed ■ Ensure competency of pharmacists and technicians who prepare IV medications ■ Use best practices for preparation of IV admixtures in addition to practices for assuring stability and sterility in USP Chapter <797> ■ Use machine-readable codes to verify accuracy of medication dispensing and filling of automated dispensing cabinets
Administering	<ul style="list-style-type: none"> ■ Require independent double checks and documentation of administration of selected high-alert medications, including pump settings ■ Standardize IV medication administration, with provisions to (1) minimize unnecessary interruptions and distractions, (2) focus on one patient at a time, (3) refer to an accurate medication administration record at the bedside, (4) engage the patient or parent and family members in medication administration process, (5) use two patient identifiers, (6) trace tubing to the body before administering medication into tubing, and (7) label distal and proximal infusion sites when using pumps with multiple channels or multiple pumps (e.g., for epidural medications, enteral nutrition) ■ Ensure competency of staff who prepare and administer IV medications ■ Involve patients and families in IV medication safety and provide written scripts to guide interactions between healthcare providers and parents ■ Use clinical tools customized for high-risk patient populations (e.g., dose calculators for pediatric patients or patients with renal insufficiency) ■ Limit the preparation of IV admixtures by nursing staff to life-threatening emergencies and preparations with limited stability ■ Use intelligent infusion devices (e.g., smart pumps) with dose-limiting feature enabled
Monitoring medication use and medication-use processes	<ul style="list-style-type: none"> ■ Have antidotes, supportive medications, dosing, and administration information as well as resuscitation equipment immediately available in patient care areas ■ Establish baseline and ongoing monitoring procedures for selected parenteral, high-alert medications (e.g., anticoagulants, insulin, vasopressors, oncologic agents) so that medication ordering is linked with appropriate laboratory test results

TABLE 16-3. (CONT'D)

Priority IV Medication Safety Practices

Step in Medication-Use Process	Priority IV Medication Safety Practices
	<ul style="list-style-type: none">■ Establish standard operating procedures for communication at the time of patient transition from one care setting to another to provide for continuity of care and medication reconciliation■ Establish standard operating procedures for communicating about and responding to actual or suspected medication errors■ Use data from intelligent infusion devices and information systems to improve medication-use processes

ISMP: Institute for Safe Medication Practices; IV: intravenous.
Source: Originally published in Proceedings of a summit on preventing harm and death from IV medication errors. *Am J Health-Syst Pharm.* 2008; 65:2367-79. American Society of Health-System Pharmacists, Inc. All rights reserved. Adapted with permission from Table 1.

TABLE 16-4.

Issues Associated with IV Drug Delivery Systems

Product Type	Benefits	Problems	Safety Rank
Manufacturer ready-to-use	Low risk for contamination, ease of use, and dispensing; maximum available expiration dating	Products not available for special populations; pharmacoeconomic data lacking; frozen products may require thawing	1
Outsourced ready-to-use	Can customize dose for each patient; low risk for contamination	Cost analysis suggested; requires advance planning and storage	3
Point-of-care activated	Works well with automated cabinets; maximum available expiration dates	Products not available for special populations; cost analysis suggested; risk of inactivation errors	2
Pharmacy compounded	Can customize dose for each patient; significant quality control; labeled in accordance with hospital standards	Risk of contamination; significant operational requirements related to USP Chapter <797>	4
Non-pharmacy compounded at point-of-care	Can customize dose for each patient, immediate availability	High potential for error; low compliance with regulatory requirements; labeling typically handwritten or absent; risk of contamination	5

Source: Originally published in Sanborn MD, Moody ML, Harder KA, et al. Second consensus development conference on the safety of intravenous drug delivery systems—2008. *Am J Health-Syst Pharm.* 2009; 66:185-92. American Society of Health-System Pharmacists, Inc. All rights reserved. Adapted with permission from Table 2.

- Concentrations and strengths of high-alert medications are standardized and limited.
- Pharmacists verify the patient's age and weight as well as the mg/kg or mg/m² dose prescribed.
- Pharmacists recalculate the dose before preparing or dispensing medications.
- Pharmacists verify the components of pediatric/neonatal sterile preparations prior to adding them to the solution rather than by the syringe pull-back method.
- Pharmacists and technicians who prepare pediatric parenteral solutions, and nurses who administer them, have specialized training and demonstrated competency.
- Automated compounding devices are used to prepare parenteral nutrition and complex electrolyte solutions.
- A clinical pharmacist is present on patient care units to participate in rounds and provide input when administering medications.
- A smart infusion pump with an activated drug library is used to administer pediatric parenteral solutions that contain (or are) high-alert medications.
- Bar-code scanning is used in the preparation of IV doses as well as to verify patients and medications before administration.
- Two nurses independently verify the patient, drug, dose, attachment, pump settings, and infusion rate before administering high-alert parenteral drugs.
- A nurse traces the line from the medication/solution to the patient to verify attachment before administration of pediatric infusions.

Special precautions for parenteral therapy should also be undertaken for other susceptible patient groups including cancer, transplant, and geriatric patients.

KEY POINT . . .

Special populations such as pediatric, cancer, geriatric, and transplant patients require special precautions for parenteral therapy.

. . . SO WHAT?

Interventions targeting patient populations at greatest risk of adverse outcomes of parenteral therapy can be more cost-effective than treating everyone the same.



SUMMARY

Parenteral drug therapy can be highly beneficial for patients but can be riskier than other routes of administration. Healthcare givers must be highly trained and conscientious in carrying out institutional procedures to minimize the risks of parenteral drug therapy. The complexity of modern parenteral therapy (e.g., with automated pumps, toxic drugs, risky administration sites) make training healthcare personnel and holding them accountable to procedures all the more important. Leaders in healthcare institutions in which parenteral drug therapy is employed are responsible for the policies, procedures, and competency of their personnel. Leaders in healthcare institutions that serve pediatric, cancer, or geriatric patients must take extra precautions in developing policies, procedures, and personnel competency measures.

SUGGESTED READING

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CHAPTER REVIEW QUESTIONS

1. Which of the following would be considered parenteral routes of administration?

- a. Intradermal
- b. Intravenous
- c. Epidural
- d. All of the above

Answer: d. Any injectable route that is administered through the skin is considered parenteral.

2. In their orders, physicians must specify all the information necessary to compound a parenteral drug.

- a. True
- b. False

Answer: b. For parenteral drugs, physicians often order just the active ingredient, dose, route, and regimen without specifying the diluent, concentration, or rate of administration.

3. Which of the following forms of infusion access is appropriate for IV therapy lasting more than a week but less than a month?

- a. Peripheral, short
- b. Peripherally inserted central catheter
- c. Peripheral, midline
- d. Implanted port

Answer: c. Short peripheral catheters are used to administer short-term IV therapy (<72–96 hr). Peripherally inserted central catheter lines are used to administer IV therapy lasting weeks to months and up to 1 year.

4. Which of the following is the most commonly used parenteral route?

- a. Intravenous
- b. Intramuscular
- c. Subcutaneous
- d. Intrathecal

Answer: a. The intravenous route is commonly used because veins accommodate a larger volume of injection, a wider variety of active ingredients, and more predictable blood levels.

5. Infusion rates can be impacted by temperature and solution viscosity when which of the following types of infusion pumps is used?

- a. Elastomeric chambers
- b. Syringe pumps
- c. Peristaltic pumps
- d. Piston-cylinder pumps

Answer: a. The infusion rate when using elastomeric chambers can be impacted by temperature, solution viscosity, catheter size, fill volume, and pump height.

6. Which of the following requires special precautions to prevent glass particulates from entering a compounded sterile preparation?

- a. Syringe
- b. Cartridge
- c. Ampul
- d. Vial

Answer: c. When ampuls are broken at the neck for opening, many small glass particles fall into the solution. Special placement of needles with the ampul or a filter needle is required to avoid withdrawal of glass particles that can be injected into a compounded sterile preparation.

7. Which of the following is true about “smart pumps”?

- a. Smart pumps have been implemented in over 90% of hospitals.
- b. Smart pumps alert the caregiver if those settings are outside of recommended parameters.
- c. Soft limits have been shown to be more effective at limiting adverse drug events than hard limits.
- d. The ISMP and ASHP recommend the use of smart pumps for all hospital infusions.

Answer: d. The ISMP and ASHP recommend smart pumps for the infusion of high-alert IV medications. As of 2012, 77% of all U.S. hospitals reported use of smart pumps.

8. During what part of the medication-use process do most parenteral medication errors take place?

- a. Prescribing
- b. Administering
- c. Compounding
- d. Dispensing

Answer: b. According to MEDMARXSM data from 2002 to 2006, 58% of parenteral medication errors originated during the administration step of the medication-use process.

9. IV infusions are more often associated with medication errors than IV bolus doses.

- a. True
- b. False

Answer: b. IV bolus doses are more often associated with medication errors. Errors with IV bolus administration are generally attributed to incorrect rates of administration.

10. Which of the following medications is NOT considered to be a vesicant drug or class?

- a. Vancomycin
- b. Normal saline
- c. Chemotherapeutic agents
- d. Hypertonic saline

Answer: b. Vancomycin, chemotherapeutic agents, and hypertonic saline—extravasation of these fluids can cause substantial tissue damage and necrosis.

CHAPTER DISCUSSION QUESTIONS

1. What makes parenteral therapy so complex?
2. Why is it important for a pharmacist to be aware of the characteristics of different infusion sites and pumps?
3. Name and discuss some procedures, devices, and systems that make parenteral therapy safer.
4. Discuss the pharmacist's role in promoting safe preparation and administration of parenteral therapy.
5. Why do different patient populations (e.g., pediatric patients, elderly patients) need customized procedures to maintain their safety during parenteral therapy?

CHAPTER 17

Leadership and Management

David A. Holdford


LEARNING OBJECTIVES

After completing this chapter, readers should be able to:

1. Define leadership and contrast it with management.
2. Discuss what it takes to be a leader.
3. Identify ways to develop leadership skills.
4. Describe six common leadership styles.
5. Identify situational characteristics that might require different leadership styles.



KEY TERMS AND DEFINITIONS

- **Attitude theory:** A theory stating that the beliefs leaders hold about people greatly influences both the manager's behavior and the followers' responses. The theory divides leaders into two categories; Theory X leaders and Theory Y leaders.
- **Behavioral theories:** A group of leadership theories that argue the greatest predictors of leadership effectiveness are the behaviors and abilities people learn over time. They all revolve around the degree to which leaders are task- or follower-oriented.
- **Big L leaders:** The label that is used to describe individuals in formal positions of authority.
- **Emotional intelligence (EI):** A group of soft skills critical for productive interactions with others. It is comprised of self-awareness, self-regulation, motivation, empathy, and social skills. These qualities help confer the ability to apply different leadership styles to different situations.
- **Follower-oriented leaders:** The leaders who express greater concern for the follower than the task at hand. These leaders demonstrate supportive behavior.
- **Leadership:** The process through which an individual attempts to intentionally influence another individual or group in order to accomplish a goal.
- **Leader:** A term used to describe individuals who influence by setting direction for others, communicating a common vision, and motivating and inspiring followers. Considered different but closely related to the term manager.
- **Little L leaders:** The label that describes people with influence who do not possess a formal position of authority.
- **Manager:** A term used to describe people who influence by providing order and consistency through the activities of planning, budgeting, organizing, staffing, controlling, and problem solving. Considered different but closely related to the term leader.
- **Power:** Ability to influence. Consists of six commonly recognized types: formal, reward, punishment, expert, charismatic, and informational.
- **Situational theories:** A group of theories that attempt to understand, explain, and predict the role of context in effective leadership. According to these theories, the greatest predictor

of leadership effectiveness and success is the situation faced by leaders and how they react to it.

- **Structure:** The degree to which a leader frames responsibilities and goals for achieving tasks. It consists of setting goals, providing training, defining expectations, setting limits on behavior, and establishing rules and procedures to be followed.
- **Supportive behavior:** The degree to which a leader indicates respect and concern for followers—treats them as human beings, watches out for their welfare, and expresses appreciation for their contributions.
- **Task-oriented leaders:** Leaders who focus on accomplishing the assigned job with much less concern about the followers who accomplish the job. Task-oriented leaders concentrate on providing the necessary structure followers need to complete their work.
- **Trait theories:** Description of a group of theories that argue the greatest predictors of leadership effectiveness and success are the traits and dispositions with which people are endowed at birth or develop early in life.



INTRODUCTION

The concept of leadership is widely discussed as critical to the future of institutional pharmacy practice, but serious concerns have been raised about a looming leadership shortage.^{1,2} It has been estimated that up to 5,000 new health-system pharmacy leaders will be needed in future years.³ At the same time, students and pharmacists are less willing to seek leadership positions for a broad range of personal and professional reasons.³

Leadership should be seen as an everyday activity of all pharmacists and pharmacy students. Nurturing the “everyday leader” should be a goal where all pharmacists show leadership in effectively influencing the behavior of physicians, nurses, pharmacy technicians, interns, and others.⁴ To achieve this goal, pharmacists and pharmacy students must understand their leadership responsibilities and their capacity to lead. Leadership skills must be well understood and nurtured in the profession to build everyday pharmacy leaders.

Despite an extensive number of leadership papers written in pharmacy, most discussions deal with the topic in abstract, personal ways. The typical leadership article presents lessons learned from the personal experience of a leader. Common themes in these papers are exhortations for pharmacists to develop a vision, be a servant to others, and influence change, but they rarely present easily applicable lessons for individuals with little leadership or life experience. Although these papers may inspire, they tend to lack an evidence-based discussion of the subject.

This chapter presents a description of major leadership concepts in the literature. It distills the extensive leadership literature into a limited number of pages geared to individuals with no previous leadership training or education. By necessity, it emphasizes explanation over comprehensiveness. Still, it is evidence-based because it is founded on an extensive understanding of leadership theory and research. The goal is to offer pharmacists and students lessons that can increase leadership effectiveness.

WHAT IS LEADERSHIP?

There are numerous definitions for the term *leadership*. One of the most concise and useful definitions defines **leadership** as “the process through which an individual attempts to

intentionally influence another individual or group in order to accomplish a goal.”⁷⁵ This definition calls attention to the following key issues associated with leadership:

- **Leadership is a process** — It is a series of actions exerted by individuals to accomplish goals. As with any good process, leadership should effectively accomplish goals, efficiently use people and resources, and be respectful of individuals involved in or affected by the process.
- **Leadership is intentional** — Leadership does not just happen. It requires deliberate effort on the part of a leader who must willingly accept responsibility and take action. *Leadership requires exerting influence.* Influence can be accomplished in a multitude of ways, from the transactional (e.g., “Do this, and I will give you that.”) to the inspirational (e.g., “Here is our purpose. Let’s achieve it!”).
- **Leadership centers on people (i.e., leaders, followers) and the relationships between them** — Good leadership accomplishes its goals in a way that develops and strengthens long-term relationships. Strong relationships based upon trust help to establish and build follower commitment to goals.
- **Leadership is goal-directed** — The ultimate purpose of leadership is to achieve desired goals. In healthcare, leadership demands the balancing of multiple goals—to the organization’s mission, the people in the organization, and the individuals served.
- **Leadership should be for the common good** — Good leaders maximize utility to society. This means that tyrants and despots like the highly influential Adolf Hitler can be deemed poor leaders because they damage the common good.

KEY POINT . . .

Leadership is a process that should effectively accomplish goals, efficiently use people and resources, and be respectful of individuals involved in or affected by the process.

. . . SO WHAT?

Leadership is not a person or an outcome. It is a process. It is practiced by individuals to achieve an outcome and relies on others to achieve those outcomes. Leaders should be judged both on the process used and the outcomes achieved. A good process respects the human beings involved, because it helps establish and maintain commitment toward a leader’s vision.

Also, disrespect for individuals is contrary to the common good.

SOURCES OF LEADERSHIP POWER

A fundamental element of leadership is the willingness and ability to use **power**, defined as the ability to influence. Leaders influence others by exerting different sources of power available to them, and individuals become leaders through their willingness and ability to wield that power. Indeed, the more power one has, the more potential influence and ability to lead.

However, the ability to influence is not enough. Some people choose not to use their power to influence change. In pharmacy settings, many managers and pharmacists refuse to use the power available to them to improve the profession and help their patients. Instead, they conclude that they are powerless to affect the world around them.

The power to lead others comes from many sources. Within an organization, there are six commonly recognized types of power: formal, reward, punishment, expert, charismatic, and informational.^{6,7}

Formal power: Formal power (also called *legitimate power*) is the power bestowed on a person in the form of positional authority. A pharmacist who is made director of pharmacy is given authority to hire and fire, make budgetary decisions, and set policy within the department. This power is used to accomplish organizational goals. In the hierarchy of a health system, a pharmacy director has more formal power than a staff pharmacist, and a staff pharmacist has more formal power than a technician.

Reward power: Reward power refers to one's ability to reward others who act in a desired manner. People with formal power in organizations often have the authority to reward the behaviors of individuals with pay raises, promotions, and praise. Although often associated with formal positions of authority, anyone can reward others. A subordinate who compliments a leader for gaining a pay raise for pharmacy employees rewards that behavior, and that compliment can cause the leader to fight harder for employee pay raises in the future.

Reward power depends greatly on how a reward is valued by the individual being influenced—a pharmacist whose financial situation is precarious is more subject to influence by monetary rewards than one who is more financially secure. If a leader cannot provide a desired reward to a follower, reward power is minimal.

Punishment power: The power to punish (also called *coercive power*), like reward power, usually accompanies formal authority in organizations. Punishments administered by managers can range from mild warnings to job termination. Punishment power is used to discourage undesired behaviors.

Although subordinates cannot formally punish a manager, they can punish a manager informally by withholding information, avoiding interactions with the manager, spreading rumors or negative stories, and even reprimanding the manager.

Expert power: Expert power derives from the expertise of a person who has special knowledge, skills, and experience. Expertise can be traded for influence. Individuals with computer expertise often wield tremendous power within healthcare organizations because of the reliance on information systems. Pharmacists use expert power within healthcare systems through their knowledge of drugs and drug therapy.

Charismatic power: Charismatic power (also called *referent power*) is an individual's ability to influence another by force of character or charisma. People who are admired by others are able to exert influence through a desire of followers to emulate or please them. Charismatic power is another source of power that is not exclusive to managers. Mahatma Gandhi was one of the great leaders of the 20th century, but he never held a formal leadership position.

Information power: Information power comes from the possession of critical information needed by others. It differs from expert power, which deals with abilities and expertise. In this information age, a person who controls information can exert considerable power. Savvy pharmacists and managers cultivate information sources in organizations who can inform them about organizational politics and upcoming events. This information is often critical to the success of pharmacy initiatives.

LEADERSHIP WITHOUT FORMAL AUTHORITY

Individuals in formal positions of authority have greater potential to influence others. White⁴ refers to these individuals as **big L leaders**. Big L leaders typically have more power

because they have additional resources available to them such as greater access to information and more contact with other influential people. Nevertheless, formal authority does not necessarily make one an effective leader.

A title only gives more opportunities to influence. If the power available to formal leaders is misused, no one will follow. Indeed, followers may even actively oppose individuals in formal positions of authority. In the short run, people may be able to get away with abusing their formal positions by taking credit for the work of subordinates, showing favoritism, disrespecting the humanity of workers, or doing any other number of things. But over time, abuse of formal power damages a leader's effectiveness.

In the end, leadership cannot be awarded or assigned by a formal position of authority. It must be earned. People who are placed in a position of authority, such as director of pharmacy or supervisor, have very little power to influence others if they do not effectively utilize the various forms of power available to them. The ability to lead is based on the perceptions of others. If people believe that a leader has power, they will choose to follow. A title cannot make one a leader, neither can a person declare himself or herself to be a leader. Only followers can decide who will lead them. Maxwell said it best, "The only thing a title can buy is a little time, either to increase your level of influence with others or to erase it."⁸

In a similar vein, people do not have to possess a formal managerial position to lead. Without a managerial title, staff pharmacists can still use reward, punishment, expert, charismatic, and information power to influence change in organizations. White⁴ calls these individuals **little L leaders**. In many pharmacy organizations, informal leaders wield substantial power—leading change from the bottom up. In fact, effective pharmacy leaders rely on these little L leaders—from developing initiatives to enhance clinical services on the nursing units to new ways of running the pharmacy. Indeed, front-line pharmacists are now expected to be leaders in their everyday responsibilities.⁹

KEY POINT . . .

"The only thing a title can buy is a little time—either to increase your level of influence with others or to erase it."⁸

. . . SO WHAT?

A title gives formal power to a leader and the ability to reward and punish, and it also provides access to information unavailable to those without titles (e.g., personnel files). However, the ability to reward and punish is limited because it is constrained by an organization's policies and culture. Heavy-handed use of rewards and punishment to manipulate followers is typically discouraged in organizations.

Information power is also tempered because a formal title causes followers to withhold information for fear of being punished or not receiving a reward. A title simply provides an opportunity for a leader to establish the trust and commitment of followers to pursue a common vision for the pharmacy. If that trust and commitment is lost, followers may ignore or even resist the leader.

CONTRASTING LEADERSHIP AND MEMBERSHIP

Leadership and management are two distinct but related activities. The concepts are often confused because they both seek to bring about change in organizations by influencing behavior. In truth, the distinction may be irrelevant because organizations need individuals who are both good leaders *and* managers. Nevertheless, the distinction can highlight different strategies employed in influencing individuals.

According to Kotter,¹⁰ **managers** exert influence by providing order and consistency. This is accomplished through the activities of planning, budgeting, organizing, staffing, controlling, and problem solving. Each is critical to day-to-day operations, especially when conditions are calm and change is unnecessary. Conversely, managerial tasks and the order and consistency associated with them are less useful in turbulent and changing circumstances, because adaptability is more important in responding to fluid circumstances.

Adaptability is typically the role of leaders. **Leaders** excel at coping with change, setting direction for others, communicating a common vision, and motivating and inspiring followers.¹⁰ Leaders exert influence by relinquishing much of the **structure** and order of managerial tasks and encourage followers to take responsibility for their work and work settings. Leaders provide vision and direction to organizations, and they attempt to inspire followers to work independently, without much direction.

Thus, the distinction is that *leaders focus on getting people to commit to a common goal, while managers concentrate on getting people to take action toward that goal*. Accordingly, the difference between leaders and managers lies in the degree of commitment expected from followers.

For managers, commitment is less important than compliance. Managers want people to do what they are told. They are less interested in their reasons for doing so. In fact, a manager may care little whether people want to do something—only that they do it.

On the other hand, leaders seek commitment over compliance. They are interested not only in behavior but also in feelings, motivations, thoughts, and perceptions associated with behaviors. Since mental processes are so integral to behavior, they are necessary to bring about maximum effort in workers. If leaders can capture the hearts of workers, greater commitment to goals and tasks will result.

Figure 17-1 illustrates the fundamental differences between management and leadership. Pharmacy managers push the staff to complete tasks by providing an organized framework of rules and controls to guide them. This framework is backed up by a system of rewards and punishments for acceptably completing the tasks. The problem is that systems based on rewards and punishments may encourage action, but they rarely encourage high levels of commitment needed to rise to the challenge of extraordinary or changing conditions.¹¹ For example, budget cuts and staff shortages may require significantly greater effort by the staff with no increase in pay and deteriorating working conditions. Stress, uncertainty, anxiety, and conflict can complicate the situation. Responding under these conditions often takes more commitment to the pharmacy organization than is generally inspired by a manager.

Commitment is better “fired up” by leaders who have gained the trust and respect of followers. Leaders pull followers toward a shared vision (e.g., patient health). The steps for achieving this vision are left largely to the followers.

Although there is value in differentiating leaders and managers, the dichotomy may be trivial in the end because pharmacy leaders must effectively employ push- and-pull strategies depending on the circumstances. Even the most motivated followers need to be pushed sometimes. Both management and leadership are essential to the success of organizations, and neither is necessarily more important than the other. Actually, the dichotomy may really be illustrating different styles of leadership rather than two separate concepts. Therefore, the remainder of this chapter will view leaders and managers to be essentially the same thing and use the terms interchangeably.

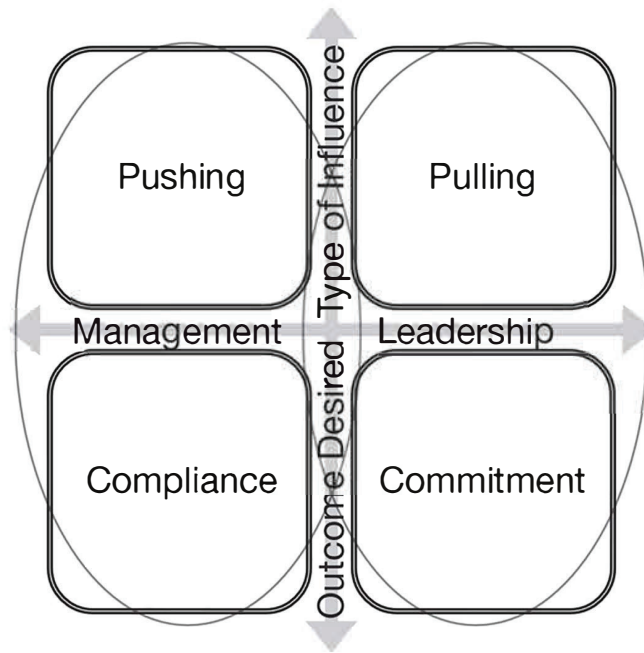


FIGURE 17-1. Contrasting leadership and management.

Source: Courtesy of David Holdford.

LEADERSHIP THEORIES

Leadership theories can help pharmacists understand and explain problems faced in influencing change. Theories supplement pharmacists' common sense and intuition when deciding which courses to choose in various situations. They allow pharmacists to apply the best evidence available from what is known about influencing individuals and groups.

Theories assist in exploring why some leaders are effective and others are ineffective. They help in assessing the reasons some leaders act the way they do and can aid in developing strategies that enhance the leaders' impact. Theories make it easier to identify leadership characteristics, behaviors, and responses to situations that need to be monitored. The challenge is to understand the basics of theories and to determine how well a particular theory applies to a situation. A basic understanding of leadership theories assists in recognizing common leadership problems and potential solutions. No single theory explains every situation. Nor can it provide cookbook answers to complex problems. Instead, it offers insight that can be used to develop nuanced solutions to leadership dilemmas.

Leadership theories can help answer the following questions: (1) What should we look for in selecting an effective leader? (2) What characteristics and behaviors are associated with good leaders? (3) Under what conditions do different leadership behaviors work best? (4) How can pharmacists improve their own leadership effectiveness?

Most leadership theories can be categorized as relating to the nature of leaders, the general behaviors in which they engage, and their responses to changing situations (**Figure 17-2**). The categories overlap because the major variables—leader, behaviors, and situation—are not independent of each other.

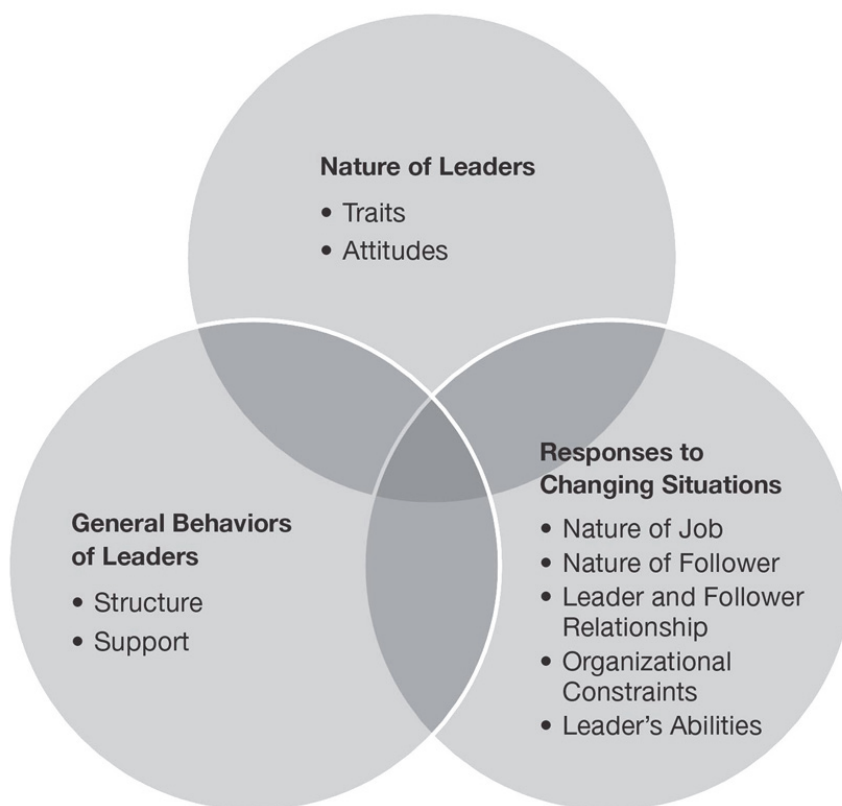


FIGURE 17-2. Variables influencing effectiveness of leaders.

Source: Courtesy of David Holdford.

NATURE OF LEADERS

Theories that deal with the nature of leaders attempt to identify what characteristics are associated with effective leaders. They can be used to select good leaders or developed over time.

Trait theories are a group of theories arguing that the greatest predictors of leadership effectiveness and success are the traits and dispositions with which people are endowed at birth or develop early in life.¹² By the time a person reaches a leadership position, these characteristics are difficult to obtain or to change.

Not so long ago, people believed that leadership capabilities were hereditary. If individuals had royal blood, they were thought to have a capacity to lead. Over time, however, objective observers noticed that royal bloodlines bore little relationship to the ability to lead. In fact, an argument can be made that leadership positions awarded on the basis of heredity can lead to the inbreeding of genes and ideas, both of which can hinder the ability of an individual to effectively lead others.

Many studies have attempted to identify specific traits in people that might be predictive of leadership capability. It was believed that if these traits were identified, they could be used to screen for good leaders. For example, leaders might be selected on the basis of intelligence quotient (IQ), if IQ could be shown to consistently predict good leadership ability. Thousands of studies have explored physical, social, personality, and task-related

traits in leaders. The traits studied include physical ones such as height, age, and attractiveness; social ones such as charisma, charm, tact, and popularity; personality ones such as adaptability, assertiveness, and emotional stability; and task-related ones such as the drives to excel, accept responsibility, and take initiative. Reviews of the literature suggest that the most desirable traits in leaders are drive, motivation, integrity, self-confidence, intelligence, and knowledge.^{12,13}

But, the relationship between these traits and good leadership has not been found to be strongly predictive. Lord et al.¹⁴ observed that the relationship between these traits and leadership capabilities is weak and inconsistent at best, making many traits poor predictors of good leaders. Intelligence, for instance, may be seen in many good leaders because a sharp mind is needed for many of the technical demands of leaders (e.g., complex problem solving, understanding complex systems). Yet, there are also many intelligent people who are terrible leaders because they lack self-control, interpersonal skills, or any other equally important capabilities of leaders.

A different theory dealing with the nature of leaders considers their attitudes toward followers. **Attitude theory** states that the beliefs leaders hold about people greatly influence both the manager's behavior and the followers' responses.¹⁵ The theory divides leaders into two categories; Theory X and Theory Y leaders.

Theory X leaders believe that people are generally lazy, lack ambition, avoid responsibility, and seek security instead of challenge. Based on this attitude, Theory X leaders believe that they must carefully watch and manage the people they lead. Tight controls must be placed to keep them busy. The best way to keep them at their job is to tell them what to do, reward them when they do what they are told, and punish them when they do not. A Theory X manager's phrases commonly include, "If I don't keep after them, they will slack off!" "They don't care about this place." "Why should I compliment them? They should be lucky to have a job!" Thus, coercive and controlling leadership methods are common with Theory X leaders.

In contrast, *Theory Y leaders* generally believe that people are not lazy. Instead, they believe that people are ambitious about things of importance and will achieve fantastic results when properly challenged. Consequently, Theory Y leaders act quite differently toward followers than Theory X leaders. Theory Y leaders treat followers with respect and ask as much from followers as they ask of themselves. They challenge followers to achieve and assume that followers will succeed. A Theory Y manager's phrases might include, "When I give my employees the right conditions and tools to do a job, they always impress me." "How do you think we should handle this problem? I value your judgment." Consequently, these managers prefer democratic, coaching, and supportive leadership techniques.

KEY POINT . . .

If a leader perceives and treats followers as respected professionals, they will reward his or her faith in them by acting as professionals.

. . . SO WHAT?

The social science literature, including education and management, indicates that human beings tend to live up to or down to other people's expectations of them.

Yet, personal and cultural factors often lead us to develop negative perceptions of our fellow man or woman. This can cause leaders to expect the worst in followers.

Low expectations can push leaders to micromanage, continually question, and act in a bossy manner toward followers. This typically leads to a vicious cycle in which followers respond by acting up, thereby justifying the leader's attitude.

The take-home lesson from attitude theory is that a leader's attitudes toward followers can act as a self-fulfilling prophecy. If a leader perceives followers to be lazy and inept, he or she will treat them that way. And when followers are treated as lazy and inept, they will act that way. On the other hand, if a leader perceives and treats followers as respected professionals, they will reward his or her faith in them by acting as professionals.

GENERAL BEHAVIORS OF LEADERS

Behavioral theories recognize that knowing the nature of leaders provides only a foundation for understanding leadership. It is really the knowledge of the behaviors associated with good leaders that can help in identifying and training them. Behavioral theories argue that the greatest predictors of leadership effectiveness are the behaviors and abilities that people learn over time.⁵ Behavioral theories attempt to answer the question, "What leadership behaviors are most effective?" A variety of behavioral theories have been proposed,¹⁶⁻¹⁹ but they all revolve around two primary dimensions of behavioral orientation adopted by leaders: task- and follower-orientations.

Task-oriented leaders focus on accomplishing the assigned job, while concerns about the followers involved in the job take a back seat. Task-oriented leaders concentrate on the important work of providing the necessary **structure** (defined as setting goals, providing training, defining expectation and limits on behavior, and establishing rules and procedures) that followers need to complete their work.

A degree of task orientation in leaders is essential because followers need some structure to complete most tasks. Still, there is a point where structure is no longer useful and becomes restrictive—even irritating. A pharmacist who continually checks up on technicians every few minutes and frequently interrupts their work with unsolicited advice or suggestions will be seen as overbearing and unhelpful.

Follower-oriented leaders focus less on the job at hand and express greater concern for the follower in words and actions. Such leaders actively support followers by treating them as human beings—not as cogs in a machine attempting to achieve some task. These leaders demonstrate **supportive behavior** by showing respect, gaining trust, demonstrating consideration, and being friendly and approachable.

Both orientations are necessary in organizations, but extremes in either orientation can be problematic. Too much focus on the task may cause followers to chafe at the restrictions. It can lead followers to label the leader as a "micromanager" or "slave driver." On the other hand, too much emphasis on the followers may result in failure to meet deadlines and goals. Most leaders try to balance a task orientation with a follower orientation. The appropriate behavior depends on the situation faced by the leader.

RESPONSES OF LEADERS

Situational theories are a group of theories that attempt to understand, explain, and predict the role of context in effective leadership. According to these theories, the greatest predictor of leadership effectiveness and success is the situation that leaders face and how they react.⁵ Traits, abilities, and behaviors are important, but they are seen as situation-specific. In one circumstance, certain traits and behaviors serve a leader well, while in another they may be disastrous. An understanding of the role of context can help leaders adapt to the dynamics of a leadership situation.

Although individual situational theories vary in content and emphasis,²⁰⁻²³ they generally agree that the appropriate leadership style depends on the job, the followers, the relationship between the leader and the led, organizational constraints, and the leader's abilities.

- **The nature of the job** — Jobs can be classified as (1) routine and nonroutine or (2) structured and unstructured. Leading people in routine, structured tasks requires different strategies than nonroutine, unstructured tasks. Simple tasks such as counting, lifting, and reading instructions require different oversight than more complex professional tasks like designing therapeutic plans or evaluating the source of a medication error.
- **Follower characteristics** — Some followers are highly motivated, energetic, willing to accept responsibility, and competent. These individuals may need little direction and structure in their jobs, while unmotivated and less capable people require close oversight and direction.
- **Relationship between leader and followers** — A strong relationship based on mutual trust and respect gives leaders the ability to collaborate and cooperate as a team. A bad relationship leads to suspicion, second guessing each other's motives, and adversarial interactions.
- **Organizational constraints** — Leaders are often constrained by organizational policies and procedures, corporate culture, and lack of time and resources. Thus, leaders are often hindered in their ability to communicate with, hire, fire, discipline, and reward staff members.
- **The leader's abilities** — Some leaders are more capable and experienced in dealing with leadership situations than others. A leader's ability to adapt to changing situations helps to adjust to different tasks, followers, and organizational constraints.

Leaders have little control over many factors influencing leadership situations. For the most part, leaders cannot substantially change the nature of the job, the characteristics of the followers, or the organizational constraints. Most pharmacy leaders “inherit” their workers and are given tasks that must be accomplished within the organization's constraints. According to situational theory, leadership success depends more on the leader's ability to adapt to a situation than the ability to change it.

KEY POINT . . .

Leadership success depends more on the leader's ability to adapt to a situation than the ability to change it.

. . . SO WHAT?

In the short term, it is difficult for pharmacists to change the nature of their jobs, followers, or organizational constraints. Therefore, they must adapt to circumstances in how they relate to followers and the leadership actions they take.

STYLES OF LEADERSHIP

Although many styles of leadership have been proposed over the years, just a handful of basic leadership styles have been identified: coercive, transformational, affiliative, democratic, pacesetter, coaching, and bureaucratic styles.

- **The coercive style** — A coercive (or *directive*) leadership style uses rewards and punishments to influence behavior.²¹ This type of leader is very task-oriented and controlling of others. Of all leadership styles, the coercive style appears to be the least effective in the majority of situations when used as the primary form of leadership.²⁴ Coercive leaders tend to create an “us-versus-them” environment in which followers feel manipulated and disrespected. Followers become frightened or resentful. They avoid enthusiastic participation in new initiatives or programs because of a fear of making mistakes or a perception that their input is not appre-

ciated. Instead, they wait for the leader to tell them what to do and are likely to say, “I just do what I’m told.”

Although often considered ineffective when used as the primary leadership style, coercive leadership is essential as a supplement to other styles. Coercion is sometimes necessary to have individuals assume undesirable but necessary responsibilities. It is also indispensable for dealing with difficult individuals who can damage the productivity of the team. Coercion can be critical in crises, such as when a business is failing and people need to be frightened into changing their work practices. Fear can be a potent motivator in getting people to change entrenched behaviors. For some employees, a threat of suspension or termination may be the only way to change poor work habits. Nevertheless, even under these conditions, coercive leadership should be used sparingly and for limited periods.²⁴

- **The transformational style** — The transformational style mobilizes people toward a vision articulated by a leader.²⁵ Transformational leaders rely on charismatic power, not rewards and punishments, to influence others. They influence others because followers identify with them and their message. Martin Luther King is an example of a transformational leader. King had a dream of what society could be like in America, and through actions and words he inspired millions to make that dream their own.

The transformational style has been found to be very effective in many situations.²⁴ Transformational leaders can inspire people by clearly defining how their work fits into a larger vision for the organization. This, in turn, maximizes the commitment of followers to the vision and energizes them to seek the best path for achieving it. Feedback from the leader focuses less on the process of achieving goals and more on the outcomes, encouraging individuals to innovate and take risks.

The transformational style can fail when the leader is unable to articulate a clear vision. Not every leader is good at doing this. When done poorly, attempts at *inspirational leadership* may be seen as pompous or out of touch. Such a leader will not be able to inspire others.

- **The affiliative style** — The affiliative style of leadership revolves around meeting the emotional needs of followers. It focuses on people, whereas coercive leadership focuses on the task.²¹ Affiliative leaders seek happiness, harmony, and, ultimately, mutual loyalty between leaders and followers. They attempt to build trust by demonstrating respect to others and communicating openly. They offer positive feedback for good work to build confidence and self-esteem. When they are critical, it is provided with the greatest care and concern for an individual’s feelings. Some pharmacy managers mistakenly assume that positive feedback will cause employees to slack off in their work, so they offer only criticism. In reality, positive feedback can enhance productivity by improving communication, loyalty, trust, and innovation.

At the same time, overreliance on the *affiliative style* can have negative effects. Followers who hear only praise will not know when they need to improve their behavior. Poor performance can go uncorrected if followers feel that mediocrity is acceptable. It can also lead to a sense of entitlement.^{26,27} Concerns have been voiced that recent generations of workers have received so much praise from their parents, teachers, and sports coaches that they expect “kudos for just showing up.”²⁷ It has been stated that overreliance on kudos has turned some young adults “into narcissistic praise-junkies”²⁷ who become insecure in the absence of regular compliments.

Whether this is true or not, all workers—young and old—need structure to do their jobs. Therefore, affiliative leaders need to supplement supportive behaviors with styles that offer more structure.

- **The democratic style** — Leaders who practice the democratic style give followers a say in decisions that affect their work lives. They solicit input from followers and attain their buy-in for major decisions and initiatives. This approach generates a sense of ownership by the staff in an organization's goals, nurtures the generation of ideas by including more individuals in the process, and helps build mutual trust and respect.

On the other hand, democracy can be frustratingly inefficient. It often leads people to debate trivial issues and haggle over decisions rather than take action. Another pitfall is that reaching consensus leads to compromises that produce less than optimal results. This is a real problem under the pressure of deadlines or when individuals lack the qualifications to help with the decision. Finally, some leaders use the democratic style to avoid making difficult decisions (i.e., those that might have a negative impact on a leader's career). Instead, they attempt to shift responsibility—and potential blame—to followers.

The key is to choose those situations where democratic leadership works well and does not work well. The democratic style works optimally when there is sufficient time for the democratic process to unfold, the best course is uncertain, and followers are sufficiently competent to contribute. When these conditions are in place, the democratic leadership style can be very successful.

- **The pacesetting style** — Pacesetting leaders set extremely high performance standards for both followers and themselves.²¹ Pacesetters lead by example—demonstrating effort and sacrifice and asking the same of others. If the pacesetter puts in long hours or gives up weekends for work-related projects, everyone else is expected to do the same. In essence, the pacesetter says, “Do as I do.” Followers who cannot keep up with the leader are replaced by others who will.

Pacesetting leaders are often praised as admirable, and the pacesetting style is adopted by many pharmacy leaders. It is a common style adopted by people who have been in the military or participated in competitive athletics. When applied appropriately, a pacesetter's leadership style often builds credibility with followers by setting a good example.

The problem is that the pacesetting style can have an unintended negative impact on morale and performance.²⁴ A pacesetter's demands for total job commitment can seem

KEY POINT . . .

When pacesetting leaders do not supplement actions with clear statements of expectations, followers are left to guess the leader's intentions.

. . . SO WHAT?

It is hard to argue with the idea of leading by example. The problem lies in the implementation. Actions may speak louder than words, but the message they send can be unintentional. Facial expressions, body language, tone and volume of voice, and other things that accompany a leader's words can be easily misinterpreted, especially in emotional situations. Words *and* actions are necessary to communicate what is expected of followers without misunderstandings.

unreasonable and overwhelming to many followers. Not everyone has the same dedication to the job as the pacesetter, especially if the leader has not inspired the followers toward a shared vision.

Another problem is that some pacesetters are not clear in what performance they expect of others, because the meaning of actions can be ambiguous. A leader may try to communicate through his actions the message, “If we all work as hard, we are going to be the best pharmacy in town.” But the follower may misinterpret the leader’s message as, “If you do not work as hard as I do, you aren’t good enough.” When pacesetting leaders do not supplement actions with clear statements of expectations, followers are left to guess the leader’s intentions. When they are not made explicit, perceived expectations of performance boil down to “be as good as me.”

Nevertheless, the pacesetting style can be effective when done well. It is effective in situations with self-motivated and highly competent followers who need little direction to complete tasks such as professional sports and medicine. It also works well when used in combination with other styles that supplement the pacesetter’s actions with explicit written and spoken communication. Finally, it succeeds when pacesetters use the style humbly, in a way that does not appear arrogant or narcissistic.

- **The coaching style** — Coaching leaders strive to develop the abilities of their followers so they can work more independently and effectively toward organizational goals. They help workers to set goals and achieve them through career development, training, and skill development. Coaches work cooperatively with the staff to improve productivity and performance, and they provide them with the tools necessary to attain success. They challenge followers and delegate tasks that help develop their skills.

Coaching can be a very effective leadership style, but it is often underutilized because managerial demands often do not permit leaders sufficient time for the slow and laborious work involved.²⁴ In many cases, it is easier for leaders to do a task themselves than teach others to do it. Yet, when subordinates learn a new skill, leaders are freed for other commitments. People who are taught to do something can take over the responsibility for it. They may even do a better job than the coach.

Coaches do better with followers who are motivated to improve their performance and mature enough to accept feedback. Coaching does not work as well when followers resist change or new ideas. It can also be ineffective in a crisis, when quick actions are necessary.

LEADERS NEED MANY STYLES

The more leadership styles a person masters, the better he or she can adapt to changing leadership situations. Leaders who have mastered four or more styles—especially the transformational, democratic, affiliative, and coaching styles—tend to establish and maintain the best working environment and show better business performance.²⁴ Equally important to mastery of the style is the ability to switch among them as the situation demands.

Some leaders adapt to their leadership deficiencies by finding environments that match their styles and abilities. A coercive leader might try to find a situation in which the staff prefers lots of structure and the tasks are routine and standardized. Or a democratic leader might seek followers who are participative and circumstances where democracy can thrive. The problem is that situations constantly change. Several famous wartime leaders—

including Ulysses S. Grant, Winston Churchill, and George S. Patton—failed as peacetime leaders because they were unable to adapt their leadership to the new environment.

Other leaders adapt by working with others who are willing and able to cover up their leadership weaknesses. This requires leaders to understand their own weaknesses, identify individuals who have skills they lack, and be willing to delegate key responsibilities to those individuals with the requisite skills. A leader who is not a “people person” may try to delegate sensitive personnel issues to subordinates with good interpersonal skills. The major problem with this solution is that it forces leaders to rely on others to do key aspects of their job. When key subordinates are not available or they leave for other jobs, the leader is left in a difficult position. The leader can also lose credibility with followers if too many responsibilities are delegated because the leader cannot or will not handle them.

A better solution may be to develop the ability to apply multiple leadership styles to different situations, which requires the leader to expand his or her style repertoire as much as possible. It also requires the leader to learn effective styles for various leadership situations.

DEVELOPING LEADERSHIP ABILITIES

It is widely accepted that individuals can learn to increase their capacity to lead. According to Maxwell,⁸ as people develop their leadership skills, they pass through four phases:

1. **Phase 1, *unaware and ineffective*** — Individuals have underdeveloped leadership skills. They may have strong opinions and be quick to offer advice, but they have done very little leading themselves and have a modest understanding of what it takes to lead others. These people have marginal impact on what goes on around them. Unless they develop their leadership skills, they will continue to be unaware and ineffective.
2. **Phase 2, *aware and ineffective*** — People have accepted leadership roles and found out how hard it is to be a good leader. They make many mistakes and are relatively ineffective. At this point, some individuals get frustrated and choose to avoid further leadership roles. Luckily, others decide to develop their leadership skills, and over time, become increasingly effective at influencing others.
3. **Phase 3, *aware and effective*** — People must work hard to apply their leadership skills, but doing so makes them steadily more effective. In this third phase, individuals consciously apply what they have learned about leading others. They make mistakes, but they learn from them. By systematically identifying and changing ineffective behaviors, they continually improve their ability to lead.
4. **Phase 4, *unaware and effective*** — Leadership is less a conscious act and more a part of a person’s life. Leadership becomes automatic, but the impact is tremendous. In this phase, leaders no longer consciously think while they influence others. They just do it, because it is a natural extension of who they are and what they want to achieve. They may still consciously assess their leadership performance and make appropriate adjustments, but for the most part, the behaviors become internalized as part of a leader’s individual persona.

ROLE OF EMOTIONAL INTELLIGENCE

Researchers have identified **emotional intelligence (EI)** as critical to leadership.²⁸ EI comprises self-awareness, self-regulation, motivation, empathy, and social skills. These qualities help confer the ability to apply different leadership styles to different situations. The greater the EI, the larger the number of leadership styles that can be appropriately

applied. Leaders who are deficient in certain components of EI are likely to be less effective in applying particular styles. A leader who lacks empathy might have difficulty using the affiliative style, while one who has poor social skills may not effectively use the coaching or transformational styles.

Improving leadership requires identifying which EI components are lacking and developing strategies for improving them. A leader who lacks the ability to use the affiliative style might attempt to improve empathetic listening skills or do a better job at relationship building. Of course, that is easier said than done, but it is possible to cultivate greater EI and consequently improve leadership. In fact, many chief executive officers of large corporations employ personal coaches to enhance their EI.²⁹ The following are some suggestions of how pharmacists can increase their EI and ability to lead:

- **Identify and work with a mentor during the early stages of one's career** — Because leadership is an art as well as a skill, it is essential to have continual and intensive coaching from an experienced leader.
- **Become a thoughtful student of leadership** — Observe others who are good leaders and reflect on what makes them so. Read up and study the topic of leadership. There are many excellent books on leadership available in bookstores and libraries where pharmacists can learn from the published experiences of others.
- **Never stop trying to understand yourself** — One way of doing so is through self-administered questionnaires such as with Meyers-Briggs Personality or EI tests. Another way is to ask for feedback from others such as your boss, coworkers, or subordinates.
- **Identify the skill sets necessary for leaders in health-system pharmacy** — Leadership is multidimensional, requiring a mix of hard technical and soft people skills. ASHP has developed a list of competencies needed for individuals seeking to move up the institutional pharmacy leadership ladder (**Table 17-1**).
- **Practice leadership** — The only way to truly learn how to lead is through personal experience. Take on leadership positions that force you to do things that stretch your capabilities. Get into the habit of replaying and analyzing your leadership experiences—both successes and failures. Analyze the causes of successes or failures and think about how outcomes might have changed under different conditions or actions. For example, if you challenge a technician to be more productive, ask yourself “Did I get the desired result with my action?” If not ask, “Why?” and “What other action could I have taken that might result in a different outcome?”

KEY POINT . . .

The only way to truly learn how to lead is through personal experience.

. . . SO WHAT?

Leadership is not a spectator sport. Unless you have taken on responsibility for leading others, you have never had your leadership skills tested. You may have conceptual knowledge about human motivation and influence, but knowing and doing are two separate things. If you want things to change in your practice setting, do not sit on the sidelines. Jump in and lead.

BARRIERS TO DEVELOPING LEADERS IN HEALTH SYSTEMS

“At present, leadership opportunities within the profession are too often impeded instead of fostered.” This occurs for many reasons. One is that many students and pharmacists do

TABLE 17-1.**Competencies Needed for Leaders in Institutional Pharmacy**

Technical Capabilities	People Skills
■ Medication-use system management	■ Human resources management
■ Pharmacy operations management	■ Leadership and vision
■ Financial management	■ Self-development and teachability
■ Information/technology management	■ Self-awareness and self-management
■ Planning and organizational skills	■ Empathy and social skills
■ Problem solving and critical thinking	■ Communication skills
	■ Integrity
	■ Commitment (initiative and persistence)
	■ Responsibility (selfless accountability for actions)
	■ Caring about others

Source: Adapted from ASHP Director of Pharmacy and Leadership Assessment Form. *American Society of Health-System Pharmacists*; 2009. Available at: www.ashp.org/DocLibrary/LeadershipAssessmentTool.aspx. Accessed March 11, 2009.³⁰

not consider leadership development to be important, desirable, and/or relevant to their lives. Some avoid leadership responsibilities to maintain an ideal balance between work and life. Others prefer to focus on clinical practice instead. Still others feel that the additional pay for formal leadership positions may not be seen as worth the extra time, effort, and stress.

The educational system is part of the problem because leadership training of students is inadequate and inconsistent.⁹ Leadership training in pharmacy schools is rarely a priority. Insufficient didactic and experiential education on the topic has led to a lack of awareness about the basics of leadership and the practical application of leadership skills. This problem is compounded because many clinical faculty members do not understand or appreciate the importance of leadership training. Thus, when teaching and mentoring students, they focus on the clinical areas of practice to the exclusion of other topics.⁹

Leadership training after graduation is also haphazard in many pharmacy work settings.⁹ One reason is that the immediate day-to-day demands of practice can absorb the entire work day, leaving little time for leadership training. Another reason is that many pharmacists in formal positions of authority are ineffective mentors and teachers. Many have received no formal training themselves, often receiving the appointment for their clinical skills or their willingness (but not readiness) to accept a formal leadership role. Indeed, bad leadership can be self-perpetuating—meaning that ineffective leaders are more likely to do a poor job developing future leaders. They will make unwise choices in selecting future leaders, provide ineffective feedback and guidance, and discourage potential leaders from pursuing formal management positions.

ASHP is actively addressing these barriers. One of the most important initiatives is its Section of Pharmacy Practice Managers, an interest group within the society that seeks to help members become more effective advocates and leaders. The section plans continuing education programs at major society meetings, sponsors special conferences that connect established leadership experts with new and potential pharmacy leaders, provides teaching materials on leadership and management, develops standards and guidelines for best practices, and offers practice tools on pharmacy management and leadership-related topics. The section has a website link at ASHP's website located at www.ashp.org.



SUMMARY

This chapter provides an overview of current leadership theories and recommendations for pharmacists. It condenses extensive leadership literature into a relatively limited number of pages. As a result, some ideas are simplified for the reader and others are left out. For example, the chapter does not address emerging leadership theories such as Servant Leadership.³¹ Nevertheless, the chapter summarizes most key concepts pharmacists need to know about leading others.

Therefore, the only thing left is for pharmacists to start their leadership journey. Every pharmacist in an organization can be a leader. Each of us has many sources of power that can be used to improve the quality of healthcare. Many problems that the profession faces could be improved if pharmacists exercised leadership at different levels of their institutions. Any leadership deficiencies can be overcome by developing leadership capabilities over time.

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CHAPTER REVIEW QUESTIONS

1. Leaders are born, not made.

- a. True
- b. False

Answer: b. False. Theories of leadership, which argue that leadership is genetic, have been generally found to be unsupported. Instead, it has been shown that leadership can be developed over time.

2. Leaders who do not have formal leadership positions are called _____ leaders.

Answer: “Little L” leaders. These are individuals with sources of non-formal power who lead change in pharmacy settings from the bottom up.

3. A leader who believes that followers have “bad attitudes” is likely to encourage “bad attitudes” and unproductive behaviors in those followers.

- a. True
- b. False

Answer: a. True. The leader above is likely to fall into the category of a Theory X leader. Leadership attitude theory states that the bad attitudes of Theory X leaders toward followers will encourage followers to match the leader’s bad opinions.

4. Leaders exert influence by their willingness and ability to exert _____ .

Answer: Power. Leadership is about influencing change, and power is the ability to influence.

5. Which of the following is LEAST EFFECTIVE in most situations when used as the primary leadership style?

- a. Coercive
- b. Affiliative
- c. Coaching
- d. Pace-setting
- e. Transformational

Answer: a. Coercive. Coercive leadership uses a push strategy that, when used excessively, can cause followers to push back either covertly or overtly. Pull strategies are more effective in gaining follower commitment.

6. Task-oriented leaders are more likely to provide support to followers than follower-oriented leaders.

- a. True
- b. False

Answer: b. False. Task-oriented leaders provide more structure than support.

7. What form of power is most associated with transformational leaders?

Answer: Charismatic power. Charisma is the ability to inspire enthusiasm. Transformational leaders inspire enthusiasm in followers by providing a vision of what is possible.

8. Effective leadership can be done without conscious effort.

- a. True
- b. False

Answer: a. True. The highest phase of leadership abilities occurs when a leader is “unaware but effective.” In this phase, leadership becomes automatic.

9. How can a pacesetting leadership style be ineffective?

Answer: When expectations of performance are not clear to followers, when demands are deemed to be unreasonable or overwhelming, or when the pacesetter is perceived to be arrogant or narcissistic.

10. A leader can be very successful in a dynamic environment with a single leadership style.

- a. True
- b. False

Answer: b. False. A dynamic environment requires the ability to apply multiple leadership styles to changing circumstances. The more styles available to leaders, the more likely the leader will be able to adapt.

CHAPTER DISCUSSION QUESTIONS

1. Describe how a good leadership process can lead to bad results, and bad leadership processes can lead to good outcomes. What implications does this have for how leaders learn from personal and professional experience?
2. What leadership styles are likely to be most effective in hospital pharmacy settings? What leadership styles have you observed in hospitals?
3. John was a pharmacist leader who was a strong believer in leading by example. He was a highly competent, hardworking director of pharmacy at a hospital. He worked long hours and did not have much of a life outside of work. John was never satisfied with the productivity of the pharmacists and technicians he supervised. He criticized them for not meeting his productivity standards and continually pressured them to work after their shift ended. He thought nothing of calling departmental meetings on weekends or after hours. What is the likely consequence? What recommendations would you give to John?
4. What types of power are available to pharmacy technicians in a pharmacy? Give examples.

Recruiting, Selecting, and Managing Pharmacy Personnel

David A. Holdford and Emily C. Prabhu

LEARNING OBJECTIVES

After completing this chapter, readers should be able to:

1. Explain the role of human resources management in providing high-quality pharmacist services.
2. Identify critical steps in the recruitment and selection of employees.
3. Discuss strategies for retaining and motivating pharmacy employees.
4. Describe the principles and practices of employee performance feedback.

KEY TERMS AND DEFINITIONS

- **Behavioral interviews:** Interviews in which applicants are asked to provide examples about past events and what they did during those events. Behavioral interviewing is based on the assumption that past behavior best predicts future behavior.
- **Equal Employment Opportunity Commission (EEOC):** The Commission charged with enforcing laws associated with the Federal Civil Rights Act.
- **Federal Civil Rights Act of 1964:** The law and its amendments that prohibit discrimination in employment hiring, promotion, compensation, and treatment based on gender, race, age, religion, and other characteristics.
- **Performance standards:** Clearly written, objective expectations of how well employees must do their jobs.
- **Position (or job) descriptions:** Descriptions that contain detailed information on training, experience, knowledge, and skills necessary for minimally acceptable employees. They establish an employee's responsibilities and necessary qualifications for a position.
- **Progressive discipline:** A series of managerial actions that escalate incrementally when unacceptable performance does not improve within a specified time period. The usual steps are a verbal warning, a written warning, a suspension, and termination.
- **Situation (or role play) interviews:** Interviews in which candidates are asked to describe what they would do if faced with a difficult imaginary situation. Situation questions assess applicants' imaginations and their ability to think up quick solutions to problems, although they do not necessarily reveal how a candidate will actually behave in real life.
- **Stress interviews:** Interviews that deliberately attempt to unnerve candidates by asking blunt, even rude questions. The questions might be delivered in an unfriendly, forceful manner and accompanied by interruptions and persistent pursuit of specific topics. Stress interviews attempt to distinguish a candidate's preparation for the interview and ability to handle stress.
- **Traditional interviews:** Interviews that engage candidates in a general conversation about themselves to gather information. Common questions are "Tell me a little about yourself" and "Why do you want to work at our institution?"



INTRODUCTION

One of the most important issues in pharmacy practice is something for which most pharmacists are least prepared and trained to deal with: personnel management. Indeed, ask pharmacists in institutional settings their greatest aggravation at work, and they will likely answer with some type of complaint about dealing with people, coworkers, other professionals, and supervisors. Successful management of people can make the difference between a smooth running pharmacy and a dysfunctional, unsuccessful one.¹

Personnel management in institutional pharmacy practice is integral to the provision of patient-centered pharmaceutical care. Managing a patient-centered institutional pharmacy depends on the clear communication of expectations to staff and timely feedback about performance. This helps minimize unproductive conflict in interpersonal relationships and builds strong professional relationships. Pharmacists in well-run and managed pharmacies are likely to make fewer medication errors and have more time and desire to effectively deal with drug-related problems. They will be less distracted, more focused, better organized, and more engaged in their work.

On the other hand, badly run pharmacies can impede patient-centered care. It is not too strong to make the statement, “Poor management of people in pharmacies kills patients.” Bad management can kill by hindering professionals’ ability to provide safe and effective care. Unengaged, inefficient, and unfocused employees make errors—and errors can be deadly in hospitals and other healthcare settings. Problem employees can also hurt teamwork by causing conflicts and disrupting the workflow. They can increase workplace tension and generally make the pharmacy a miserable place to work. In addition, problem employees tie up managers in conflict management, counseling, and supervision—time that can be better spent on other important tasks. Recruiting and retaining good employees is arguably the most important job of pharmacy managers.

LAWS AND REGULATIONS AFFECTING HUMAN RESOURCES MANAGEMENT

Most actions in the management of pharmacy personnel are influenced by laws and regulations passed by local, state, and federal governments intended to protect workers from unfair employer practices and biases toward individuals.¹ The most important piece of legislation affecting personnel management is the **Federal Civil Rights Act of 1964** and subsequent amendments to the Act. The original purpose of the Act was to outlaw racial segregation in employment and public settings. It has since been expanded to prohibit discrimination in employment hiring, promotion, compensation, and treatment of protected employee groups—those who might be discriminated against based on their gender, race, age, religion, sexual preference, height, weight, arrest record, national origin, financial status, military record, or disability.

The **Equal Employment Opportunity Commission (EEOC)** is charged with enforcing laws associated with the Federal Civil Rights Act. Although some actions of the EEOC are considered controversial (e.g., affirmative action), the EEOC can help ensure a smooth running of the pharmacy by enforcing what any good manager should already be doing—developing and implementing fair and explicit human relations management.¹ The EEOC prohibits discrimination in any of the following²:

- Hiring and firing
- Compensation and benefits, assignment, or classification of employees

- Transfer, promotion, layoff, or recall
- Job advertisements
- Recruitment
- Testing
- Use of company facilities
- Training and apprenticeship programs
- Other terms and conditions of employment

In addition, EEOC prohibits practices such as harassment of protected employee groups or retaliation against individuals for exercising their rights under EEOC rules.² Clashing with the EEOC can cause legal problems for a pharmacy and hinder efforts to recruit and retain excellent employees. Therefore, pharmacy managers need to familiarize themselves with federal and state laws associated with hiring and firing and consult with their human relations department throughout any sensitive personnel management cases. The department of human relations can review and advise manager actions on appropriate procedures to be followed and adequate documentation.

KEY POINT . . .

Poor management of people in pharmacies kills patients.

. . . SO WHAT?

Few people think about ineffective managers and management practices this way. Most realize that poor management can make the workplace intolerable or that it can waste a lot of time and resources. But few think about how it can kill patients.

But if you look at the root cause of any fatal medical error, you will see that poor management is a contributing factor. For instance, the people involved might not have been given the necessary training, tools, or feedback, or a disorganized work setting may have distracted an employee.

Pharmacists in well-run and managed pharmacies are likely to make fewer medication errors and have the time and desire to provide better service to patients and deal with their drug-related problems.

THE EMPLOYMENT LIFE CYCLE

Employment in an institution can be likened to a life cycle (**Figure 18-1**) where an employee's life at an institution begins when hired, the employee grows and matures as training and experience are gained, and the end comes when the employee terminates employment.

Each phase of the life cycle builds on the other in the growth of a productive employee. Successful recruitment and hiring make all of the other steps easier by starting with a good foundation. Suitable training and development, job design, and feedback increase job satisfaction and employee productivity. When the time comes for an employee to leave a position, it will likely be for good reasons (e.g., a promotion or retirement after a long and successful career) if all of the other steps have been done well.

HIRING

The pharmacy department shares hiring and other managerial tasks with the department of human relations (also called the *personnel department*). Human resources departments typically advertise positions, manage applications and paperwork, screen candidates, advise about legal and policy questions, check references, and extend job offers.¹ Their expertise and efforts are invaluable in freeing pharmacy managers and staff to focus on the selection process.



FIGURE 18-1. The employment life cycle.

Presence of a human resources department does not mean that pharmacists should surrender their responsibility in recruiting and choosing new employees.¹ At a minimum, pharmacists need to supervise the process because human resources personnel do not understand the needs of pharmacy practice as well as pharmacists. Furthermore, human resources personnel do not suffer the same consequences of a bad pharmacy employee choice as individuals in the pharmacy department. Human resources will not be reminded daily about a poor employee choice, but the staff in the pharmacy department will be. Hence, pharmacists should seek to maintain as much control as necessary over the recruiting and selection process.

Ideally, the recruiting process should be inclusive and allow all employees to contribute. Employees

KEY POINT . . .

Employment can be likened to a life cycle, where an employee's life at an institution begins when hired, the employee grows and matures as training and experience are gained, and the end comes when the employee terminates employment.

. . . SO WHAT?

Employees have different needs depending on where they are in their employment life cycle. At the beginning, they need a good foundation for later success. This includes an orientation to the organization's culture and developing skills needed to accomplish their jobs. As an employee progresses through the life cycle, their needs and desires change. Managers who align employee interests to the organization's needs will be more likely to have a satisfied and productive staff.

should be encouraged to recommend the position to qualified friends and professional acquaintances. They should also help review position descriptions to ensure that the descriptions are accurate and up-to-date. Employees should be involved in interviewing candidates, especially if they are going to be working with the individuals eventually hired. Including staff in the process will broaden the potential for insights into candidates and increase the chance of selecting good individuals.

THE RECRUITING PROCESS

There are numerous activities associated with recruiting qualified candidates. Job descriptions and performance standards are their center (Figure 18-1). **Position (job) descriptions** are the foundation of human relations management because they describe an employee's purpose. Clearly written and conceptualized job descriptions are essential for communicating employees' expectations. They are used in setting salaries, communicating performance expectations, and writing annual performance evaluations. They are also crucial in helping screen out unqualified candidates and encouraging qualified candidates to apply.

Job descriptions contain detailed information on training, experience, knowledge, and skills necessary for a minimally acceptable candidate. They establish the candidate's responsibilities and necessary qualifications for the position. A sample job description is included in **Figure 18-2**.⁴ The following information may be included in a position description³:

- Position title and classification
- Duties, essential job functions, and responsibilities of the position
- Education, training, experience, and licensure required
- Knowledge, skills, and abilities needed to perform the assigned duties
- Reporting and coordinating relationships
- Scope of authority (i.e., the degree to which decisions can be made without consulting a superior)
- Pay grade and salary range (optional)
- Education and training required to maintain competence
- Other specifications of the position required by law or the organization

PERFORMANCE STANDARDS

Performance standards utilize information from the job description to establish benchmarks for employee behaviors and accomplishments. **Performance standards** are clearly written, objective expectations of how well employees must do their jobs. They tell employees what to do, how well to do it, and how fast. Performance standards often utilize *SMARTER* characteristics: **s**pecific, **m**easurable, **a**chievable, **r**elevant, **t**ime-bound, **e**ngaging, and **r**ewarding (**Table 18-1**).⁵ They are used in orientation, training, performance appraisal, coaching, counseling, disciplining, and almost any other personnel management task.

Performance standards can help reduce managerial bias in interactions with employees, because they are explicit and objective performance expectations. The employee is held accountable for unambiguous benchmarks of acceptable and unacceptable performance rather than the manager's subjective perceptions. This benefits both the employee (by clarifying job expectations) and the manager (by providing a yardstick upon which to judge employee performance). That yardstick is useful in reducing employee claims against unfair treatment—it is harder to argue against objective measures of performance—and can head off charges of discrimination and bias.

Job Description

Job title: Pharmacist

Job code: XXX

Reports to: XXX

Summary of position and duties:

This individual provides pharmaceutical care to patients within the institution. This position serves as the medication expert within the organization. A strong clinical foundation and knowledge of hospital operations, including the medication distribution process, is required in addition to the understanding and application of organizational and departmental policies and procedures.

Duties specific to the job title:

1. Provides pharmaceutical care to patients.
 - Appropriately prioritizes patient care activities based on criticality.
 - Participates in interdisciplinary patient care rounds.
 - Identifies and resolves any medication therapy problems including inappropriate therapy (e.g., dose, route, frequency, duration, route of administration), therapeutic duplication, medication allergies, and clinically significant drug interactions.
 - Documents clinical interventions in compliance with organizational policies and procedures.
 - Provides concise, thorough, and timely responses to drug information requests.
 - Provides discharge medication teaching as appropriate.
2. Facilitates training of healthcare professionals.
 - Provides didactic training, including educational seminars/lectures, to healthcare professionals in training.
 - Provides experiential training to pharmacy residents and students.
 - Consistently attends educational sessions, in-services, and presentations within the organization.
3. Contributes to quality improvement.
 - Supports the organizational mission and values.
 - Participates in the development and implementation of organizational/departmental quality improvement and patient safety activities.
 - Provides appropriate handoff when needed and accepts accountability for ensuring successful information transfer occurs.
 - Serves as a connection between patient care areas and pharmacy leadership.
 - Reports medication errors and adverse drug reactions internally and externally if appropriate.
 - Represents the department on institutional/ practice area committees as needed.
4. Engages in professional self-development and scholarship.
 - Completes required continuing education credits to maintain state licensure.
 - Completes annual competency requirements by the predetermined deadline.
 - Contributes to the literature through submission of publications.
 - Maintains active membership in local/national pharmacy organizations.
 - Utilizes communication skills to provide prompt and accurate information to all customers.

Minimum requirements for position title:

- Education: Pharm.D. required
 - Experience: PGY1 required; PGY2 preferred or 5 years of equivalent experience
 - License/Certification: State Board of Pharmacy License is required
-

FIGURE 18-2. Sample pharmacist job description.⁴

TABLE 18-1.

SMARTER Characteristics

S pecific	Clear, well-defined
M easurable	Able to be quantified
A chievable	Can the standard be completed in the given time frame?
R elevant	Does the standard reflect a priority?
T ime-bound	Deadline, due date for completion
E ngaging	Involvement of key stakeholders from the start to promote accountability and involvement
R ewarding	Satisfaction on completion

Figure 18-3 provides an example of a performance standard for a pharmacist for the act of dispensing. Expected performance is detailed and quantifiable. A pharmacist who has more than two justified complaints in the process of reviewing medication orders, addressing drug-related problems, and related communications does not meet minimally expected performance. Two complaints or fewer meet minimal performance expectations.

Most standards consist of more than just two levels of performance. Other levels might be added such as “meets expectations but needs improvement,” “exceeds expectations,” and “significantly exceeds expectations.” Clear descriptions of these performance levels need to be developed and communicated to employees, so they can know exactly what accomplishments are needed to achieve a desired rating.

Because expectations of pharmacy personnel are multidimensional, standards are typically developed for various types of performance.⁶ Compliance standards require obedience to established policies and procedures such as expectations of employee attendance, showing up to work on time, and compliance with department dress code.

Other standards might deal with an employee’s temperament and ability to work with others including quality of communication, initiative and ability to work independently, and ability to work as part of a team. Standards are also set for the primary tasks of a position including the quality of work, the quantity of output, and the timeliness of completing tasks. The following characteristics are associated with good performance standards⁶:

- They must be explicit about what determines unacceptable, acceptable, and superior performance.
- They must be specific, objective, and measurable.
- Standards should be challenging but attainable. Expectations should not be so high that an employee does even try to meet the standards, but not so low that little effort is needed to achieve them.

KEY POINT . . .

Performance standards tell employees what to do, how well to do it, and how fast. They are used in orientation, training, performance appraisal, coaching, counseling, disciplining, and almost any other personnel management task.

. . . SO WHAT?

It is surprising how many pharmacy employees do not know or contribute input to the performance standards to which they are held accountable. This can be problematic when attempting to justify their contributions to the pharmacy or in responding to criticism about one’s work. When managers and employees understand and agree on standards of performance, strategies for improving output can be developed and conflict over expectations reduced.

Performance description: Dispenses medications in accordance with state and federal laws, all regulatory agencies, and departmental policies.

Minimally expected performance: No more than two justified complaints received during the year regarding serious medication errors or routine dispensing functions. This includes but is not limited to:

- Reviewing all orders prior to dispensing
- Maintaining and regularly reviewing patient medication records for potential drug-related problems
- Contacting physicians, nursing staff, and others as needed to resolve questions regarding medication orders
- Documenting actions in electronic medical record

FIGURE 18-3. Performance standard for dispensing.

- Performance must be under an employee's control. Employees should not be judged on performance failures or successes related to the system or other uncontrollable factors.
- Standards should be accepted by both the employer and employees. Disagreements over standards of performance need to be resolved. If not, conflicts over performance feedback and evaluations will likely result.

RECRUITMENT STRATEGIES

Recruitment strategies should be individualized to the type of position being filled. As a general rule, the more important the position (e.g., department chair), the more effort and time needed. Systematic recruitment planning is recommended due to the potential cost of making a bad hire. Planning should consider what has worked or not worked in past recruiting efforts. Many institutions recruit continuously even when no job openings are available, so a ready list of individuals is available when an opening occurs.^{1,3}

Recruiting individuals from within the department or from other departments has advantages over recruiting from outside of the institution. One advantage is a better understanding of the capabilities and performance of candidates. Another advantage is that it shows commitment to the development of employees. Hiring from within confirms that management respects the employees. Internal recruitment can be less expensive by precluding the need to advertise positions, pay for housing and transportation for out-of-town candidates, and pay recruiters to find qualified candidates. In addition, scheduling interviews is easier for internal candidates thereby reducing the disruption of daily work.

Internal recruitment begins very early in the employment life cycle. Indeed, even before hiring an employee, interviews should ascertain an employee's career aspirations and interests in promotion within an organization. After being hired, employees should be offered training opportunities and tasks to prepare for future roles within the institution.

Nevertheless, recruitment from outside of an institution has advantages too. The primary advantage is the potential for recruiting from a larger number of qualified candidates. Another advantage is that external candidates can inject new perspectives and ideas into the pharmacy. Without introducing outside talent into an institution, organizations can become insular and narrow-minded in their practices. To recruit individuals outside of the organization, the following methods are commonly used³:

- Advertising in professional journals, newspapers, state professional society newsletters, and electronic bulletin boards.

- Using personnel placement services provided by national or state professional societies.
- Soliciting oral and written recommendations from colleagues.
- Offering a finder's fee for hires that result from an employee referral.
- Scheduling personal discussions or correspondence with potential candidates.
- Scheduling recruitment visits to colleges of pharmacy or to facilities that conduct technician-training programs.
- Using professional recruiting firms, which typically charge the organization a percentage of the position's annual salary. In addition, recruitment advertising companies offer access to a list of job seekers for a fee.
- Familiarizing students with the organization by offering summer jobs or participating in college of pharmacy experiential rotations.
- Offering tuition assistance programs for students in exchange for future work commitments.
- Maintaining a "prospect list" of individuals applying for previous job openings, which the human resources department can often supply.
- Attending community job fairs and local or state welfare-to-work programs, and organization-sponsored events such as continuing education sessions, award presentations, or community outreach programs.

Being an employer of choice in a region makes recruiting easier. Employers of choice have a reputation for being the most desirable place to work. They can pick and choose among the best candidates for positions. Managers can help an institution become the employer of choice by earning the respect of employees, making the pharmacy a better place to work, and providing opportunities for professional growth. Managers can also lobby for adequate compensation programs for employees (e.g., salary, fringe benefits, raise structure).

APPLICATIONS AND SCREENING

The interview process typically starts when a candidate fills out a job application. The job application and any related correspondence (e.g., resume, letters of recommendation) are stored in the candidate's file.

After submitting a job application, candidates are screened for their suitability for the position. Screening is done to weed out unqualified applicants from the pool of potential candidates. Common screening criteria include lack of job qualifications (e.g., license, degree, residency, experience), poorly completed applications (e.g., misspelling, missing information, sloppy writing), and negative applicant history (e.g., felony conviction, lying on the application, frequent changes in employment).¹

After screening the candidate applications, a screening interview is generally conducted prior to offering an on-site interview. The purpose of the screening interview is to provide a quick assessment of the appropriateness of a potential candidate for a position and provides an avenue for an exchange of information between the job candidate and the employer. The human resources department or the direct supervisor for the position usually conducts the screening interviews.³ The interview may be conducted at the institution, by telephone, or at professional gatherings such as the ASHP Annual Midyear Meeting. Notes from the screening interview should be placed into an applicant's file. Once the screening interview is complete, a decision will be made regarding whether to offer an on-site interview. **Figure 18-4** provides an example of a template that may be used for candidate screening.⁴

CANDIDATE INFORMATION	
Name	Date of screen
Phone	Email
Interview Screen Information	
Job title	
Describe your prior work experience.	
What skills do you have that qualify you for the position?	
What certifications do you have?	
Interview Screen Summary	
Candidate strengths	
Candidate weaknesses	
Recommend on-site interview? <input type="checkbox"/> Yes <input type="checkbox"/> No	

FIGURE 18-4. Sample interview screen template.⁴

THE INTERVIEW PROCESS

Interviews are scheduled after identifying qualified candidates for a position. If multiple applicants are qualified, candidates are typically ranked according to their desirability. The top-ranked candidates receive initial invitations to interview, while the less-qualified candidates are commonly left in a reserve pool of backup individuals who will be invited to interview only if none of the top candidates are acceptable.

Preparation for an interview is as important for the interviewer as it is for the candidate.¹⁰ Preparations should take into account the schedules of individuals who will be involved in interviewing and use realistic estimates of the time needed in planning and interviewing. **Figure 18-5** provides a suggested list of interview preparation steps.^{1,3}

Most interviews follow a predictable number of steps. The first step consists of introductory small talk and interviewer introductions designed to put the candidate at ease. Rather than jumping immediately into the questioning, a few minutes of small talk attempts to establish some rapport with the candidate. After the small talk, interview questions are posed of the candidate.

Interviews may take place one-on-one with one interviewer and one interviewee, or they may utilize a team-based approach where a group of employees interviews the candidate. Although one-on-one interviews may take less time overall, team interviews allow multiple individuals to assess the behaviors and characteristics of the candidate to determine if the fit is appropriate.³ It is common for interviewers to employ several interview styles. Interview questions can be posed using different interviewing techniques¹:

- **Traditional interviews** engage candidates in a general conversation about themselves. “Tell me a little about yourself” and “Why do you want to work at our institution?” are common questions. This line of questioning is useful in gathering general information about the candidate.

1. All interviewees should be sent information about the position including the job description and standards for performance, the institution, local information about the city and state (if an out-of-town candidate), travel directions, and clarification about reimbursement for expenses incurred during the interview. This helps candidates prepare for the interview.
2. Objectives for the interview should be established. Objectives may vary depending on the organization's immediate needs. If the pharmacy has acute, immediate needs, only those candidates who are immediately available might be considered. In other situations, the pharmacy may be willing to wait for an excellent candidate to graduate from pharmacy school or complete a commitment made to another employer.
3. The position description and performance standards should be reviewed. These documents will form the basis of many interview questions.
4. Applications, letters, and resumes should be explored for accomplishments and credentials on which to question the candidate. Key concerns should also be noted including frequent job changes, gaps in employment, demotions, inconsistencies in history, or incomplete information on references.
5. A list of interview questions should then be developed that attempt to assess the candidate's ability to achieve job requirements specified in the performance standards. Examples of questions can be found in a variety of sources.^{3,7-9} Human resources departments are also helpful in crafting questions.
6. It is often desirable to ask a core group of standard questions of all candidates to allow interviewers to compare candidate responses. Those standard questions should then be supplemented with questions specific to the candidates' responses and unique qualifications for the position.
7. A quiet, uninterrupted interview time and place should be scheduled.
8. Coworkers should be scheduled to meet and interview the candidate.

Note: See Reference 1 for more information.

FIGURE 18-5. Steps to prepare for an interview.

- **Situation (or role play) interviews** ask candidates to describe what they would do if faced with a difficult imaginary situation. For example, "You are a pharmacist, and a technician has told you that another pharmacist just covered up a dispensing error. What would you do?" Situation questions assess applicants' imaginations and their ability to think up quick solutions to problems, although they do not necessarily reveal how a candidate will actually act in real life.
- **Stress interviews** deliberately attempt to unnerve candidates by asking blunt, even rude questions such as "We were looking for someone with more experience for this position. What makes you think that you are good enough to fill this position?" The questions might be delivered in an unfriendly, forceful manner and accompanied by interruptions and persistent pursuit of specific topics. Stress interviews attempt to distinguish a candidate's preparation for the interview and ability to handle stress. The downside is that qualified candidates might be insulted and go to other employers. In addition, stress interviews may not effectively discriminate between successful and unsuccessful individuals.
- **Behavioral interviews** seek examples of an applicant's past behavior under the assumption that past behavior is likely to predict future behavior. Specific questions are asked about past events and the applicant's involvement in the events. Applicants are asked questions that start with "Describe a situation when you had to..." or "Tell us about your worst experience..."

After the questioning phase is finished, candidates are usually encouraged to ask questions of the interviewers. Managers should be prepared to describe relevant facts about the job including opportunities for professional growth, descriptions of employee benefits, the initial salary and salary range for the position, and the employee's work schedule. Non-managers should expect questions about the daily work, general morale of employees, and the like. Interviewers should give the candidate a realistic view of the position, including both favorable and unfavorable information, to avoid overselling the position.³ At the end of the interview, applicants either meet with other interviewers or are given a tour of the facilities. If the candidate is from out of town, a tour of the area should be given, too.

After the interview, the candidate should be updated on progress with interviews. At a minimum, employer follow-up should occur after the interview expressing thanks for the candidate's interest and explaining when a decision will be made about the position. A friendly phone call to the candidate might be made to express continued interest in the candidate and answer any additional questions.

The final choice of an employee typically comes down to how well a candidate can address the following questions of the interviewers⁴:

- **“Can this person do the basic job?”** — Job openings occur because of an organization's need. The better the candidate can craft an argument that he or she is the best one for solving this need, the more likely he or she will be hired.
- **“Will the candidate make my job easier?”** — The interview process is conducted by human beings who have personal interests in how the position will be filled. The candidate who makes the best case that an interviewer will benefit by hiring him or her will have a jump on the competition.
- **“Would I want to work with this person?”** — Applicants who are likeable and able to develop rapport with interviewers enhance their chance of being selected for a position.

Before a final offer can be extended to a candidate, a background verification check should be completed. The check verifies information provided by a candidate and is typically completed by the human resources department. Information about the candidate and the candidate's responses may be checked against the following sources⁵:

- Personal letters of reference provided by the applicant
- Letters of reference provided by previous employers or preceptors (with the applicant's permission)
- State board of pharmacy records
- Academic records
- Legal background searches (when permitted by law and/or by the applicant)

KEY POINT . . .

The person who gets a position is typically determined by how well the candidate addresses the questions: “Can this person do the basic job?” “Will the candidate make my job easier?” “Would I want to work with this person?”

. . . SO WHAT?

The smartest, more technically competent person is often not the person chosen for a job. Interpersonal skills and the ability to do the basic job are sometimes more important. For example, a pleasant work environment commonly has people who get along with each other, who contribute their fair share, and who do not cause problems for employers. A candidate's chances are improved if he or she can get an interviewer to think, “I want to work with this person.”

After a candidate passes the background verification check, a compensation package is put together, and an offer extended. Job offers should be extended as soon as a hiring decision is made to prevent a candidate from accepting another position. The offer is typically made by phone because the phone is expedient and more personal than other forms of electronic communication like e-mail. If the offer is not accepted or rejected immediately, a deadline for responding is usually negotiated between the candidate and the employer. Once an offer is accepted, a starting date is negotiated and the employee works with the human relations department to complete necessary paperwork and other requirements of new employees.

RETENTION

The issue of retaining pharmacists and other pharmacy-hired employees is a major concern of institutional pharmacy managers. Indeed, the costs of pharmacist turnover has been estimated to range from more than \$20,000 to almost \$90,000.¹¹ The issue of employee retention is linked to all parts of the employment life cycle, and failure at any point of the hiring, training, or performance feedback stages can lead to the loss of a pharmacist. **Figure 18-6** summarizes a checklist that can identify areas that need improvement for retaining pharmacists and other pharmacy employees.

MOTIVATING PERFORMANCE

Once an employee is hired, a major role of a manager is to encourage superior performance and/or at least avoid discouraging it. This role can be accomplished by individuals who can apply principles of human motivation to facilitate employee performance. Ideas about human motivation are controversial, and no single theory answers all questions a manager might have about how to motivate people. However, research does provide some rules-of-thumb for pharmacists and managers.¹³⁻¹⁶ The following are some general guidelines:

- Communicate what is expected of employees in speech, writing (e.g., policies and procedures), and action. Be consistent in all communications.
- Perceptions matter. In many cases, doing the right thing may not matter if employees perceive things differently. Therefore, managers should try to understand issues from the employees' viewpoints.
- Systems for measuring employee performance need to accurately and fairly distribute rewards.
- The more a manager listens to and knows about the needs of the people with whom he or she interacts, the better the manager will be able to identify what issues are most important and likely to motivate an employee. For instance, an employee who values free time may not be motivated to take on additional challenges with monetary bonuses. On the other hand, giving additional time off in exchange may work.
- Provide positive feedback often and provide it much more than negative feedback.
- Employees who feel threatened are often less productive. A manager's threats of job loss or excessive criticism, no matter how well deserved, can cause unintended consequences in employee behavior. Threats can cause anxiety, fear, and resentment as well as distract employees from their work. Therefore, negative feedback should be used thoughtfully and sparingly. When used, negative feedback should provide explicit actions for employees to improve performance and be accompanied by supportive comments to take the sting out of the criticism.
- Include employees in decisions that affect their lives. Participation can help them gain ownership of the processes under which they work and are assessed. It can

Salaries

- Our salaries and benefits are competitive to other hospitals in our region.
- Our salaries and benefits are competitive to other non-hospital pharmacist employers in our region.
- We regularly monitor, track, and adjust pharmacist salaries (e.g., quarterly).

Employee Development

- We provide annual opportunities for our staff to obtain additional training or attend professional meetings at hospital expense.
- We provide opportunities for pharmacists to progress into areas of greater responsibility based on experience and skills.
- We promote and reward professional development growth in our performance appraisal system.
- We actively mentor new, inexperienced practitioners.

Lifestyle

- We offer preferred shifts and schedules whenever possible. We shift non-time sensitive work to fit the preferred shifts.
- We offer significant incentives to those who work non-preferred shifts.
- We meet with our staff at least annually to discuss quality-of-life issues and adjust our work environment where possible.
- We offer flexible/creative schedules when possible to meet special needs.

Practice

- Staff have the necessary tools to do their jobs—adequate references and electronic information sources, hand-held computers, space, and access to computers.
- Most of our pharmacists practice in an environment that is professionally challenging and rewarding with patient contact.
- We use automation and technicians to perform duties that do not require pharmacist knowledge and expertise.
- Our pharmacists are in a position to positively affect patient care and outcomes.

Environment

- Our staff have regular communication from management.
- Our staff have regular opportunities to communicate issues to management.
- Our management staff and other staff members are enjoyable to work with.
- Our technician staff are well trained and work collaboratively with our pharmacist staff.
- Our relationship with other professionals such as physicians and nurses is positive, constructive, and collaborative.

Note: Originally published in ASHP Guidelines on the Recruitment, Selection, and Retention of Pharmacy Personnel. *Am J Health-Syst Pharm.* 2003; 60:587–93, American Society of Health-System Pharmacists, Inc. All rights reserved. Adapted with permission.¹²

FIGURE 18-6. Pharmacist retention checklist.

help them better understand and accept how rewards are distributed and the behaviors required to receive those rewards.

- Focus on encouraging feelings of accomplishment and pride in one's work. Help them find the joy in their current job or help them develop their skills for a better job.
- Try to pay people a fair, reasonable amount and then do everything possible to encourage them to forget about their pay. A preoccupation with money distracts everyone—employers and employees—from issues that really matter.
- Help employees realize that most reward systems are unfair to someone, in some way, and at some time. Try to be seen as doing the best you can for employees given the current flawed reward system.
- Set an example for others by demonstrating pleasure in what you do.

KEY POINT . . .

Perceptions matter. In many cases, doing the right thing may not matter if employees perceive things differently.

. . . SO WHAT?

To a great extent, management is about influencing perceptions. Perceptions are reality. If employees perceive that a manager is being unfair in the treatment of employees, the reality of the situation is irrelevant to how they are going to react. Therefore, managers not only need to do the right thing, they need to be perceived as doing the right thing.

Employee Engagement

Another concept that directly impacts motivation and is essential to an organization's success is engagement. *Employee engagement* refers to an individual's dedication to an organization. Engaged employees are enthusiastic about what they do and demonstrate discretionary effort as they help an organization achieve its goals.¹⁷ Additionally, engaged staff are more likely to stay with an organization in the long-term and consistently perform high-quality work. Prior studies have found that employee engagement significantly impacts turnover, because 50% of unengaged employees will likely leave an institution within 12 months as compared to 10% of engaged employees.¹⁷ In every organization employees can be grouped into one of three different categories relating to engagement (**Table 18-2**)^{18,19}:

1. Engaged
2. Not engaged
3. Actively disengaged

TABLE 18-2.

Categories of Engagement

Category	Associated Behavior
Engaged	Produce high-quality work, innovative, team player, accountable, invested interest in the organization
Not Engaged	Puts forth minimum amount of effort, just going through the motions
Actively Disengaged	Negative attitude, unhappy, destructive to other team members

Note: See references 18 and 19 for more information.

In 2014, approximately 31.5% of employees in the United States were engaged, 51% were not engaged, and approximately 17.5% were actively disengaged. Engagement also varies among different generations with the younger generations, such as millennials, demonstrating the least engagement.^{18,19} A variety of factors also play a role in developing a culture of engagement within an organization. Alignment of an employee's role with the organizational mission and values, competence and enthusiasm, respect, recognition, and constructive feedback are critical components of fostering an atmosphere of engagement. Awareness of the different categories of engagement and associated behaviors is essential to promote a motivated, enthusiastic, and accountable workforce. Engagement is critical in an organization because it connects directly to productivity, improved outcomes, job retention, and reduced turnover.^{17,20}

PERFORMANCE FEEDBACK

Managers are judged on how well the team performs, and effective performance feedback is essential for productive and well-functioning teams. Performance feedback attempts to communicate how well employees are achieving the objectives in their job description and performance standards. It also suggests ways that performance can be improved.

Performance feedback can occur any time a manager interacts with an employee. Indeed, feedback is continually provided from a manager's words, voice, body language, and behaviors. For that reason, managers need to be continually aware of the messages they send to employees in day-to-day interactions. Awareness needs to be accompanied by self-control, too, because a misplaced comment or a poorly articulated criticism can cause unnecessary tension or communicate an unintended message.²¹

Day-to-day discussions are the most effective form of performance feedback because they are immediate and frequent. Behavior is more likely to change in day-to-day feedback because it can occur shortly after the behavior occurs. For that reason, managers often try to look for a situation that illustrates problem behavior to be discouraged or a positive behavior to be reinforced. This process can be improved if employees are encouraged to provide their view of the situation. This encourages employees to analyze their behaviors and engages them in the change process. If there is disagreement about the problem behavior, the manager should speak in terms of *perception* of the situation. Rather than saying, "This is what you did," it is better to say "Correct me if I am wrong. This is what I observed." Focusing on perceptions is less confrontational but still very effective in addressing behavioral issues. After an agreement is reached on the need to change, the employee should be encouraged to come up with a strategy to improve. Once agreed on, the manager should periodically check to see if employee performance improves.

Annual (or semiannual) performance reviews are another form of feedback to employees. Both employees and managers sometimes dread annual performance reviews because they take a lot of time and effort, can be stressful, compete with other priorities, and can be seen as a bureaucratic chore.⁶ Nevertheless, performance reviews are important because they require managers and employees to step back and think about progress throughout the year and make plans for the future. Annual performance reviews augment and summarize feedback provided by managers in day-to-day interactions.¹

Ideally, the performance review should be an exchange of information and ideas—not a report card of the worthiness of an employee.⁶ Certainly, reviews will have an evaluative component of employee performance. But equally important, they serve as a planning session for long-term employee and departmental goals.

Effective reviews should attempt to achieve several goals.⁶ They should summarize information provided to the employee in day-to-day feedback. If daily feedback has been

effective, then nothing in the performance review should be a surprise to the employee. Reviews should encourage the employee's self-appraisal and offer the employee an opportunity to communicate accomplishments that might have been overlooked by the manager. Employee performance should be recognized, and performance deficiencies should be addressed through a collaborative, dual problem-solving process. Discussion should emphasize the future instead of past performance because the past cannot be changed. Good reviews should attempt to positively affect an employee's self-esteem and improve the relationship between employees and managers. A typical performance evaluation consists of the following steps:

- Performance standards are reviewed, and any issues associated with the standards are clarified.
- Objectives from previous evaluations are examined.
- The manager evaluates past performance with the employee and expresses appreciation for any accomplishments.
- The manager discusses causes for any performance deficiencies and mutually develops strategies with the employee for improvement.
- Any long-term career goals are discussed, and strategies for achieving them are developed.
- Relevant points discussed in the interview are recorded, and both the employee and manager sign the performance review document.

Efforts should be made to avoid common appraisal problems⁶:

- Using the *recency effect*—Biased assessments may result when the reviewer bases judgments primarily on recent job performances of employees instead of on performance over the whole evaluation time period.
- Using the *halo effect*—Evaluators judge individuals based on general perceptions of the person and not objective, quantified measures of behavior.
- Trying to be nice rather than objective—Evaluators need to be objective and unbiased about an individual's performance and not think about how he or she will be perceived by the employee.
- Rating everyone the same.
- Not taking the process seriously.
- Using the review primarily to assign salaries instead of improving performance.
- Having insufficient or superficial knowledge of an employee's performance.
- Emphasizing the negatives during the review.
- Blindsiding individuals with unexpected issues that had never been brought up before in day-to-day feedback.

Reviews should be conducted with the understanding that they may eventually be challenged in institutional grievance proceedings or in legal settings. Therefore, reviews need to be procedurally and legally justifiable.⁶ This means that all statements should be factual and based on measurable performance. For instance, an employee should not be described as having a "bad attitude." More precise criticism should be offered, such as the number of complaints from nurses and co-workers about the individual's behavior. Reviews should also be based on an employee's job responsibilities and performance objectives. Thus, if an employee's dress or hairstyle is not relevant to expectations of performance, it should not be discussed. Finally, reviews should be consistent across employees so those of similar job descriptions are held to similar standards of performance.

PROGRESSIVE DISCIPLINE

Progressive discipline is a form of feedback designed to improve *unacceptable* employee performance such as absenteeism, tardiness, unprofessional behavior, violation of rules, and unsatisfactory work performance. **Progressive discipline** consists of a series of managerial actions that escalate incrementally when unacceptable performance does not improve within a specified time period. In all steps of the disciplinary process, documentation is critical, and a second unbiased individual should be present to observe all interactions. The following are the usual steps in progressive discipline:

- **Verbal warnings** — Oral reprimands about poor performance and what will occur if performance does not improve. A chronically tardy technician might receive a verbal warning that he or she is not meeting performance standards and must show up to work on time to avoid further disciplinary action. The manager should make a note about the time and place of the reprimand and what was discussed. If behavior does not improve, a written warning follows.
- **Written warnings** — Formal document of disciplinary action that should clearly describe the unacceptable behavior, previous warnings, specific expectations of future behavior to be achieved by a precise deadline, and the consequences of not meeting expectations.¹ For example, a formal warning might state, “You were verbally warned about tardiness on January 16 of this year. You have continued to be tardy at a rate above that specified in your performance standards. If you are late for work more than twice within the next month, you will be suspended for one day without pay.” The written warning makes explicit to the employee that if behavior does not improve, the next step in progressive discipline occurs: suspension.
- **Suspensions** — Disciplinary actions that force employees to take unpaid leave for a specified time period. They are designed to jolt the employee into taking action and demonstrate the seriousness of a situation. They act as a final warning that current behavior is unacceptable. The written documentation is similar to that of a written warning except that the consequences of further unacceptable behavior are more severe (i.e., termination of employment).

KEY POINT . . .

Progressive discipline consists of a series of managerial actions that escalate incrementally when unacceptable performance does not improve within a specified time period.

. . . SO WHAT?

Progressive discipline seeks to protect employees and managers by employing a structured process to managerial feedback and discipline. Employees are protected because they are provided with detailed feedback about unacceptable performance and given opportunities to improve it. Managers are protected because they are given a process of disciplinary actions that is legally defensible against charges of bias.

TERMINATION OF EMPLOYEES

Hopefully, termination will be a rare event for individuals in a pharmacy because it is a difficult experience for everybody involved. In truth, it reflects a failure of the human resources management system.

Termination of an employee means that the system failed to choose the right person for the job and/or give the employee what was needed to succeed. For the terminated employee, it can negatively impact self-esteem and damage financial security. For the manager, the termination is an unpleasant confrontation at best, and at worst, a potential lawsuit for wrongful dismissal.

The repercussions of termination can be minimized if institutional termination policies and procedures are followed and the human resources department is consulted and involved throughout the process. Policies and procedures protect both the employee and the manager, and the human resources department can prevent common errors from occurring. In all cases, termination should be done with compassion and in a manner that seeks to maintain the employee's dignity and self-respect. The process should be well documented and witnessed.



SUMMARY

By necessity, a single chapter can provide only a quick overview of recruiting, selecting, and managing pharmacy personnel. The subject is complex and can require years of experience before one gains sufficient expertise. This chapter highlights only the key issues of managing pharmacy personnel that are so critical for serving the patient. Hiring, training, performance feedback, and other key elements of managing people are interrelated such that all must be done well to get the most out of pharmacy personnel. Individuals who are well managed are more likely to be productive and enjoy their jobs. Competent, productive employees in a pharmacy are better able to provide pharmaceutical care and achieve better health outcomes for patients.

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CHAPTER REVIEW QUESTIONS

1. The following is a good performance standard: “All employees should try not to be late for work.”
 - a. True
 - b. False

Answer: b. False. The above standard is neither specific in the expected behavior (trying to not be late for work is a vague expectation) nor quantitative (it is not clear how many times being late for work is unacceptable).

2. **The purpose of screening job applicants is to identify the best candidate for the position.**
- True
 - False

Answer: b. False. The purpose of screening is to eliminate all applicants deemed unqualified for the job.

3. **Interview questions should be based upon:**
- Position descriptions
 - Performance standards
 - The interviewer's personal interests
 - Details about the candidate's resume and application

Answers: a, b, c, and d. Any of the above can and should inform the interview. Answer c might be controversial based on the argument that questions about personal interests might lead to bias. However, the process is conducted by human beings, and personal interests cannot and should not be excluded from the interview.

4. _____ interview questions are based on the assumption that what people have done in the past is predictive of what they will do in the future.
- Stress
 - Behavioral
 - Situational
 - Traditional

Answer: b. Behavioral. Behavioral interview questions ask candidates to provide examples of previous accomplishments or behaviors assuming that they are more predictive of future performance than questions answered under stress, based on made-up situations, or general discussions about oneself.

5. **Perceptions matter more in interactions between managers and employees than the truth.**
- True
 - False

Answer: a. True. Perceptions are reality in dealing with human beings. For example, a manager's actions that are perceived as unfair by employees, even if judged fair by objective observers and standards, will suffer the same consequences of a manager who is truly unfair.

6. **Employees should be included in all managerial decisions.**
- True
 - False

Answer: b. False. Employees should be included only in managerial decisions that affect their lives. Selection of coworkers is an example of a decision that affects employees' lives, so they need to be involved as much as possible.

7. **Which of the following methods of performance feedback are most effective, on average, in influencing employee behavior?**
- Day-to-day feedback
 - Annual performance evaluations
 - Progressive discipline

Answer: a. Day-to-day feedback. Day-to-day feedback immediately and frequently reinforces desired behavior and discourages undesired behavior. Annual performance evaluations occur too rarely to have long-lasting impact on daily performance. Progressive discipline is not typically used for the average employee and, therefore, is unlikely to have much influence on the behaviors of most employees.

8. Greater pay motivates better performance in employees.

- a. True
- b. False

Answer: May be both true and false. Many might argue that the answer is true because the answer is simply common sense and the foundation of our economic system where those who produce more should receive greater rewards. Others might say false by responding that not everyone is motivated to receive greater pay or that better performance is often not rewarded with more pay. However, the question is much more complex than one might see at first glance. The answer to this question probably can never be definitively answered because of the complexity of human behavior and the convoluted way that humans respond to incentives. For one thing, the statement above does not define how much pay, how the pay is linked to good performance, how well performance measures distinguish good performance from not-so-good performance, how motivated employees are to put in the additional effort needed to achieve the pay, or the host of other variables affecting motivation. Therefore, good leadership and management must support pay-for-performance systems in personnel management need.

9. Which of the following actions might indicate an ineffective performance review?

- a. The manager emphasizes the award of a pay raise during the review.
- b. The manager focuses on all of the negative behaviors of the employee throughout the evaluation period.
- c. The employee and manager engage in mutual problem-solving on identified performance weaknesses of the employee.
- d. The manager links performance assessment to the employee's performance standards.

Answers: a and b. Both answers are associated with ineffective performance reviews. Discussions about pay increases may be important to the employee, but they can distract from the real purpose of performance reviews—to assess past performance and plan for ways of improving performance in the future. Focusing on the negative during performance evaluations will leave employees demoralized and overshadow any achievements made during the year. Performance evaluations should be mutual problem-solving sessions between employees and managers. Evaluations should assess performance against established standards of performance and result in mutually agreeable strategies for improving future performance.

10. The primary purpose of progressive discipline is which of the following?

- a. Improve minimally acceptable employee behavior to behavior that is superior.
- b. Get rid of employees who are not contributing members of the team.
- c. Encourage employees to change from unacceptable to acceptable performance.
- d. Document employee punishments to avoid being sued.

Answer: c. The purpose of progressive discipline is to motivate employees to move from unacceptable to acceptable performance. It is not meant for employees who are at least minimally acceptable. Its primary purpose is not to get rid of employees either, although that may be the end consequence of the process. The primary purpose of progressive

discipline is not to provide cover to managers to avoid being sued. If avoiding lawsuits is a goal, one could probably achieve that goal by doing nothing to address poor employee performance.

CHAPTER DISCUSSION QUESTIONS

1. What should go into a clinical pharmacist's performance standards?
2. Do you think the EEOC hinders or helps pharmacists serve their patients? Why?
3. Do you think that your annual reviews have always been fair? Explain.
4. Provide an example from your life that supports or refutes one of the motivational rules-of-thumb described in the section *Motivating Performance*.
5. Do you think that progressive discipline is used more to mend the behaviors of problem employees or to get rid of problem employees? Why?

CHAPTER 19

Preparing for Careers in Hospitals and Health Systems

Thomas P. Reinders and David A. Holdford

LEARNING OBJECTIVES

After completing this chapter, readers should be able to:

1. Identify what training and skills are necessary to succeed in hospital and health-system pharmacy practice.
2. Compare the various training and educational options for hospital and health-system pharmacy practice.
3. Contrast graduate education with residencies and other forms of experiential training.

KEY TERMS AND DEFINITIONS

- **American Pharmacists Association (APhA) Career Pathway Evaluation Program:** The program that provides a process for exploring pharmacy careers and offers resources for making informed career decisions.

- **ASHP Midyear Clinical Meeting and Exhibition:** A national annual meeting in December where individuals interested in post-graduate training can attend the Residency Showcase.
- **Curriculum vitae (CV):** Detailed information about an individual's job qualifications and experiences. It differs from a resume because it is typically longer and more detailed (more than two pages).
- **Internship:** On-the-job training experience for students enrolled in pharmacy school.
- **Portfolio:** A collection of information about an individual designed to provide a comprehensive picture of experience, accomplishments, and training. It typically contains actual work completed, for example, a written project or poster presentation that can showcase one's capabilities.
- **Resume:** Document summarizing relevant education, training, and job experience. It differs from a CV because it is short (one or two pages).

INTRODUCTION

Students often start pharmacy school with just a vague idea about where they will practice after graduation. Initial career plans often evolve as they progress through their professional education. The curricula at pharmacy schools exposes them to the vast variety of options available within the profession.

Pharmacists can practice in independent community pharmacies, super markets, corporate pharmacy chains, mass merchandisers, mail order pharmacies, specialty pharmacies, hospitals, long-term care facilities, government institutions, managed care settings, and many other locations. The career choices within each of these locations (e.g., clinical pharmacist, manager, specialist) make choosing a career path quite challenging.

Successful student pharmacists begin by taking an early and active role in career planning. They sample their options by shadowing practicing pharmacists; working part-time as interns in pharmacies; volunteering in clinics that provide care to medically underserved communities; becoming involved in student organizations that offer service learning opportunities; and actively networking with classmates, professors, and practitioners.

KEY POINT...

Your ability to identify and compete for hospital and health-system practice positions is influenced by steps you take in pharmacy school.

...SO WHAT?

If you have no idea what you want to do with your life upon graduation, you may be at a serious disadvantage in regard to your career. Many of your classmates and colleagues have been taking steps to prepare for a career in hospital and health-system pharmacy practice. They have chosen their coursework and practice experiences to teach them concepts and skills that will prepare them to practice. They have built a resume of experiences and accomplishments that differentiate themselves from other potential job candidates. They have interviewed for residencies and other jobs in hospital and health-system practice and probably have offers in hand. However, if you are still at least a year or two from graduation, you still have time to take the steps that can help you obtain a career in hospital and health-system pharmacy practice.

PLANNING A CAREER PATH

So, how do you know which career paths might be right for you? The steps are relatively straightforward:

1. Assess your personal strengths and weaknesses.
2. Develop an understanding about yourself and the kind of life you want to live.
3. Learn about different career choices and how they match your strengths and weaknesses.
4. Think about how different career choices lead to the kind of life you want to live.
5. Chose a direction and start taking steps toward your chosen career path.

The self-assessment steps 1 through 3 are necessary for the completion of steps 4 and 5. Indeed, it is difficult to choose the right career without knowing about yourself and what you want in a career. Therefore, self-assessment is essential. Students consider the self-assessment suggestions in the following discussion.

Take Time for Personal Reflection

Turn off your mobile device, computer, gaming device, and any other electronic or non-electronic distraction and reflect upon your work, education, and daily activities. Analyze your daily activities, your choices, and outcomes of your choices. Did things turn out the way you planned or hoped? Did you achieve anything of importance, have fun, or learn anything new? What were the day's highlights and lows? Did anything surprise you or challenge your personal assumptions? How would you do the day differently if you had a chance?

Taking time for personal reflection is a way for individuals to think seriously about what they are doing with their lives and their paths. It also helps them consider alternatives to their current career paths.

Get Input from Others

Ask most successful people how they got to where they are, and they will tell you about a critical conversation they had with someone who put them on their path to success. That person may have been a parent, teacher, family friend, employer, or even a stranger. The key is that a person said the right thing, at the right time, in a way that crystalized the person's career path. In most cases, these conversations were by chance, and the resulting impact was serendipitous. The key to effective self-assessment is to seek out these conversations and learn from them.

When seeking feedback, resist the urge to talk only to people who will tell you what you want to hear. Feedback is most useful when it challenges your beliefs and even makes you uncomfortable. Try to avoid arguing against criticisms, and be honest about your weaknesses.

Schedule informational interviews with people who have jobs that sound interesting to you. Informational interviews are simply scheduled meetings with knowledgeable people that seek advice about careers, industry opportunities, daily work life, and what is needed to succeed. It differs from a job interview because it is conducted to gain insight, not a job. It is also more of a low-stress conversation than a critical assessment about one's employment potential.

Listen to all advice but be selective on what you accept. Many well-intentioned people offer terrible advice. The key to career success is to discriminate good advice from bad.

Conduct a Personal SWOT Analysis

A personal SWOT analysis is a systematic assessment of your strengths (**S**) and weaknesses (**W**) as a potential pharmacist and an evaluation of opportunities (**O**) and threats (**T**) in the pharmacy profession. Information from a personal SWOT analysis can help guide you in making career choices. The S and W portion of your SWOT analysis can be guided by personal reflection and input from others as described above. The O and T evaluate the current and future conditions that you will face after graduation. **Table 19-1** lists questions you should try to answer.

Understand Your Options

Step 4 of planning your career path entails understanding the various career options in pharmacy. Your options can be considered in numerous ways, including:

- Type of employer (e.g., hospital, pharmacy chain, independent pharmacy, managed care, mass merchandiser, grocery store, pharmaceutical company).
- Practice setting (e.g., retail business, outpatient clinic, inpatient, corporate office, home office, mobile office, laboratory, long-term care facility, call center, mail order).
- Values and practices that make up an organizational culture (e.g., organization's mission, company support for workers, commitment of employees).
- Daily job activities (e.g., work variety, autonomy, job meaning and significance).
- Schedule (e.g., 9-to-5, weekends, rotating shifts).
- Career and salary potential.
- Opportunity for professional development.
- Current and future job security.

TABLE 19-1.

Questions to Answer in a Personal SWOT Analysis

STRENGTHS	WEAKNESSES
<ul style="list-style-type: none">■ What do you do better than anybody else?■ What specific skills and knowledge do you have (e.g., work experience, major accomplishments)?■ What freedom do you have to act (e.g., no geographic ties, little debt)?■ What is your reputation among your peers, coworkers, and professors?■ What is your school's reputation among potential employers?	<ul style="list-style-type: none">■ What type of work do you avoid due to a lack of confidence or preference?■ What weaknesses do your peers, coworkers, and professors perceive in you?■ What pharmacist skills do you feel least confident about (e.g., writing)?■ What bad habits do you have (e.g., tardiness, speaking without thinking)?■ What strengths do your classmates and coworkers have that you do not?
OPPORTUNITIES	THREATS
<ul style="list-style-type: none">■ The Affordable Care Act is causing changes in the practice of pharmacy.■ The shortage of primary care physicians may open doors for ambitious pharmacists.■ Changes in technology may allow pharmacists to access more patient information in any work setting.	<ul style="list-style-type: none">■ Residencies are becoming increasingly competitive.■ Job openings for pharmacists are less common.■ The number of graduates from pharmacy schools may be greater than the need in the healthcare market.

Source: Courtesy of David Holdford.

Throughout your tenure as a student pharmacist, there should be many opportunities to learn about your options in the profession. **Table 19-2** illustrates the possibilities for learning both inside and outside of the classroom over a typical 4-year pharmacy school curriculum. The only reason why students might remain in the dark about their options is due to inattention or procrastination.

A valuable tool to assist you is the **American Pharmacists Association (APhA) Career Pathway Evaluation Program**.¹ You can access the program from the career tab on the APhA Academy of Student Pharmacists website (www.aphanet.org).

Many pharmacy schools require their students to complete exercises in the Career Pathway Evaluation Program, so many students are already familiar with it. These students would probably be well served by reviewing their findings periodically to clarify their own career preferences. If you have never completed the program, you can explore it on your own by going to the website. You will benefit from the time taken to complete the survey and examine the exercises.

The Career Pathway Evaluation Program offers individuals the opportunity to assess which career options best suit their personal interests and strengths. A unique feature of the program is the opportunity to compare one's rating of 48 critical factors common to pharmacy practice (e.g., work schedule, job security, prestige and opportunities for advancement) with the ratings of actual pharmacists in a variety of practice settings.

Table 19-3 lists critical job factors that were highly rated by staff pharmacists, clinical specialists, and pharmacist managers practicing in health-system settings including hospitals, home health care, and long-term care. The table also provides a short assessment of the presence of these factors in hospital and health-system pharmacy practice. Findings from

TABLE 19-2.**Opportunities to Learn About Career Options in a Typical 4-Year Pharmacy School Curriculum****ACTIVITIES**

Activity	Goal
<i>Learning about Career Options</i>	
Shadow practicing pharmacists	Observe day-to-day practice in various work situations
Participate in Introductory Pharmacy Practice Experiences	Develop introductory skills and gain exposure to practice sites
Talk with mentors	Ask questions and get advice about opportunities
Review professional association and employer websites	Discover what issues are important in different work settings
Acquire internship experience	Learn about practice setting in depth
Complete career assessments like the American Pharmacists Association (APhA) Career Pathway Evaluation Program	Understand preferences for careers
<i>Preparing to Compete for a Residency</i>	
Conduct informational interviews	Have formal 10- to 15-minute interviews about career paths with mentors and potential employers to gain specific career advice
Take elective courses related to your future practice goals	Develop skills, knowledge, and accomplishments
Acquire internship experience	Develop a reputation for competence that others might be willing to talk about
Participate in Advanced Pharmacy Practice Experiences	Develop a reputation for competence that others might be willing to talk about
Become active in student organizations	Develop a track record of leadership, service, and accomplishment
Prepare and update career statement, resume, curriculum vitae, and electronic portfolio	Provide documented evidence that describes your accomplishments and potential for future success
Review pharmacy residency programs	Understand residency options
Take specific steps to apply for residency	Take action to get a residency

Source: Courtesy of David Holdford.

the pathway program indicate that pharmacists in hospital and health-system practice, on average, are intellectually challenged by the work itself and the individuals with whom they work. They have a chance to apply what they learned in pharmacy school, and they enjoy competitive compensation, good working conditions, and the opportunity for professional development. If these are things you desire in your career, the opportunities in health-system settings might be right for you.

TABLE 19-3.**Important Critical Factors for Health-System Pharmacists**

Critical Factor	Assessment
Collaboration with other professionals	Pharmacists spend a significant amount of time during their daily activities in working with other health professionals, especially physicians and nurses. Because the health professionals are usually within the same facility and have access to a patient's health record, there is constant written and verbal communication concerning the drug therapy of patients. Collaboration in this setting is important since the success of any health system depends on its ability to function as a collaborative unit.
Variety of daily activities	Pharmacists have a great variety of tasks and duties during a routine day. The health-system setting spans a wide range from ambulatory care to critical care. The medication-related needs of patients for this continuum of care creates variability. Although some activities can be repetitive, there is always a balance between routine and challenging tasks and duties.
Multiple task handling	The health-system setting is a dynamic environment where pharmacists are not always able to work on a single task until it is completed. The setting, by its very nature of promptly dealing with the acute needs of patients, often requires the pharmacist to handle multiple tasks.
Applying medical knowledge	Pharmacists in the health-system setting have an opportunity to apply their medical and scientific knowledge on a daily basis. There is a constant need for accurate and reliable drug information related to the medication needs of patients in this setting.
Job security	Job security and stability is apparent because there is a continuous need for pharmacists in the health-system setting. Pharmacists with specialized knowledge and skills are provided even more security.
Income	Compensation is important to pharmacists. During the past decade, the salaries for pharmacists in this setting have increased so that they are often equivalent to salaries offered in the community setting. Pharmacists with additional credentials and management responsibilities usually receive additional compensation.
Benefits (vacation, health, retirement)	Benefit packages are important to pharmacists seeking employment. Overall, the health-system setting provides generous benefit packages. Some benefits (e.g., additional vacation, travel funds, child care, fewer weekend shifts) are a major reason that some pharmacists have been attracted to this setting.
Professional involvement	Professional involvement is important to pharmacists in this setting. Pharmacists are concerned about the respect for their work and seek to share ideas and knowledge among peers. Opportunities are provided to attend meetings and events related to the profession. Health-system employers generally encourage and reward professional involvement.
Autonomy	Pharmacists in this setting like their ability to make independent decisions about their practice activities. Pharmacists are viewed as medication-use experts, and their opinions about medications are trusted by other healthcare professionals. Although independent decision making is evident, pharmacists in this setting favor the ability to provide their recommendations while functioning as a healthcare team member.

TABLE 19-3.**Important Critical Factors for Health-System Pharmacists**

Critical Factor	Assessment
Self-worth	Satisfaction based on recognition and feedback is important to pharmacists in this setting. Likewise, it is important to have a high level of confidence in the quality of their work and to fulfill personal and professional goals.
Additional training	Health-system settings are known to encourage and promote additional training for their employees due to the number of disease conditions and treatments, advances in technology, and trends in this setting. This provides the opportunity for professional growth, which can enhance career satisfaction and lead to additional compensation. Many health-system employers will provide some or all of the expense associated with position-related education and training.
Interaction with colleagues	There is a high level of interaction among colleagues within the health-system setting. This involves interaction with staff within the pharmacy as well as all other health professionals providing patient care.

Source: Reprinted with permission from APhA Career Pathway Evaluation Program for Pharmacy Professionals. Washington, DC: American Pharmacists Association; ©2007.

CHOOSING A CAREER IN HEALTH-SYSTEM PHARMACY

At some point in their education, students need to pick a general direction for their career. That choice does not need to be irrevocable. Instead, we recommend exploring career opportunities at first without locking in on any specific one in the beginning. Head in a general career direction that interests you, but do not close yourself off to any option. Do not say, “I do not need to know about X, because I am going to be practicing Y.” Take advantage of all of the options your education provides you, within the classroom and outside of it. Learn as much as you can, stay focused on your studies, network, join organizations, and have fun.

No matter where you practice in pharmacy, you will be able to build a challenging and satisfying career. But if you think you want to work in hospital and health-system settings, you should actively head in the general direction of preparing yourself for a residency.

The chief reason is that the residency is increasingly becoming essential for entry into health-system pharmacy practice. Key professional organizations like the American College of Clinical Pharmacy (ACCP) and ASHP have strongly advocated residency training as a prerequisite to entering into direct patient care practice. Many employers have taken this advice as a mandate and hire only residency-trained pharmacists for clinical positions in their institutions. Others have strong preferences for residency-trained pharmacists.

Risk of Procrastination

Therefore, if a career in hospitals and health systems is still a possible career path for you, start as soon as possible to acquire specific skills and experiences that can help you compete for residencies after graduation. The competition for residencies and entry-level positions in health-system settings can be fierce, and opportunities typically go to those who are most prepared.

As educators, we have seen a lot of students put off their career choices until late in their educational process. In fact, students often postpone any active career planning until the experiential phase of their last year of pharmacy education. In their advanced pharmacy practice experiences (APPEs), they are exposed to dynamic pharmacist role models who actually practice pharmacy in team-based surroundings (i.e., just like the professors say in pharmacy school). Then they ask themselves, “Why didn’t I know about this earlier?”

Procrastination about career planning is often based on perfectly good reasons like:

- “I don’t know enough about my options.”
- “I am afraid of making the wrong choice.”
- “I might miss out on other good opportunities if I narrow my focus.”

Procrastinating is also an ingrained behavior for many students that may work in pharmacy school but hurt them badly in career planning. Many have learned in school that they can put off studying for a test or completing an assignment and still get a respectable grade by cramming or pulling an all-nighter. However, procrastination in career planning is a risky habit—especially when it comes to seeking a position in health-system pharmacy practice.

To compete for residencies and the best entry-level positions, you need to compile a portfolio of experiences that demonstrates you are able to succeed after graduation. Individuals who start their portfolio early have more opportunities to address gaps and build a personal story of accomplishment.

Students no longer have the luxury of procrastinating and still getting what they want. There are now many candidates for the best jobs in hospitals and health systems. The number of pharmacy school graduates has increased more than 70% in recent years,² and the number of applicants for residencies far exceeds the available number of openings.³

Students who choose to skip the residency path and apply for hospital pharmacy positions right out of pharmacy school face even greater competition. Current pharmacist vacancy rates in health systems average around 2%.⁴ New graduates may be competing with residency graduates and experienced hospital pharmacists for available positions.

Do not be discouraged, however. One out of every four pharmacists works in health-system pharmacy settings, so there are jobs out there. They just may require extra effort to attain.

KEY POINT . . .

Take advantage of all of the options your education provides you—within the classroom and outside of it. Learn as much as you can, stay focused on your studies, network, join organizations, and have fun.

. . . SO WHAT?

It is hard for pharmacy students to develop a good resume if they confine themselves to the classroom and study areas. Well-rounded resumes demonstrate a life outside of the classroom in addition to academic accomplishment. Moreover, the relationships made in pharmacy school can continue long after graduation. The pharmacy profession can be a small world, and the quality of relationships developed during the years at school can pay off in the future.

GAINING EXPERIENCE

IPPEs and APPEs

Recent changes in the accreditation standards for schools and colleges of pharmacy offer all students a chance to learn about health-system pharmacy. Schools now require exposure to practice settings during the initial years of a pharmacy student’s education—through introductory pharmacy practice experiences (IPPEs). This requirement affords an opportunity for all students to explore pharmacy practice in a health-system setting. Also required

in the latter part of the curriculum, students complete APPEs in health-system pharmacy practice. APPEs in health-system pharmacy provide more in-depth observations about practice in this setting and require students to demonstrate common practice competencies such as the preparation of intravenous (IV) drug products and responding to drug information requests from physicians.

Even if students have no intention of practicing in hospital and health-system settings, they need to pay attention during these rotations because many of the skills can be useful in non-hospital and health-system settings. For instance, some independent pharmacists prepare IV infusions for small hospitals and home healthcare companies, and chain pharmacies now employ clinical pharmacists in specialty pharmacy settings. General knowledge about hospital and health-system pharmacy practice can also be useful to non-hospital and health-system pharmacists in handoffs of patients between practice settings (e.g., medication reconciliation when moving from hospital to community locations).

Student Organizations

Involvement in student pharmacist organizations offers opportunities to learn more about hospital and health-system pharmacy practice. Some organizations, such as the Academy of Student Pharmacists, represent all facets of professional practice, while others represent specialized practice such as student chapters of the American Society of Health-System Pharmacists (ASHP). Joining either type of organization can provide a starting point for learning more about the practice of the profession in a health system. Taking leadership roles within professional organizations can help in developing leadership skills and offer better professional networking opportunities. Some student ASHP chapters offer shadowing experiences with health-system pharmacists, similar to the exposure provided during IPPEs.

Didactic Curriculum

Students gain information about health-system practice as part of their didactic curriculum. Formal lectures and required readings offer an entry point for exploring health-system practice. Some schools and colleges provide required and elective courses revolving around health-system practice. These courses offer readings from the health-system pharmacy literature, presentations from invited hospital and health-system pharmacist lecturers, and field trips to health-system pharmacies. The clinical pharmacy curriculum also presents information about hospital and health-system practice in both required and elective courses (e.g., cardiology, critical care, oncology).

Some schools and colleges offer specialized educational tracks for students who wish to practice in health systems and/or to pursue a residency. If your school does not offer one

KEY POINT . . .

Even if you have no intention of practicing in a hospital and health-system setting, pay attention during health-system IPPEs and APPEs because many of the skills learned in these rotations can be useful in non-hospital and health-system settings.

. . . SO WHAT?

Many faculty members at schools of pharmacy are aware of the exasperating declaration made by students, “I don’t need to know X because I am going to be practicing in Y.” In truth, no one really knows what the future holds for them or what they really need to know. However, many conditions once treated only in hospitals now are handled in ambulatory or long-term care settings. That trend is likely to continue.

Therefore, many of the skills learned during health-system IPPEs and APPEs may come in handy in the future for almost any pharmacy practice setting.

of these tracks, you can always work with your faculty and administrators to develop your own personal track, arranging a portfolio of practice experiences that will allow you to be competitive when seeking a residency.

Internships

Internships in a health system provide a basic understanding of hospital and health-system practice. This can be especially helpful when pursuing a pharmacy residency upon graduation because it provides a sound introduction to the basics of practice and training in relevant skills. Residency candidates with additional experience in health-system practice may have an advantage over those with limited hospital and health-system practice experience.

Mentors

Mentors can be an invaluable source of support and encouragement for student pharmacists or new graduates. Ask them about their career path and what they would recommend to someone who is just starting out in the profession. Just be aware that they will likely be passionate about their chosen area of practice and may advocate for this path over other practice areas. Talk with many mentors and peers, listen to what they say, and make your own choice.

Professional Meetings

Consider attending local, state, and national meetings to learn more about the profession and begin building a network of colleagues. Attending the **ASHP Midyear Clinical Meeting** is valuable for students seeking a residency. Most residency program directors participate in a residency showcase program during the meeting. The event is structured to allow you to meet program directors, staff, and current residents. The residency showcase is an important first step in learning about the variety of programs and to begin preparing a list of questions related to pursuing a residency.

Internet

Do not forget the Internet. Pharmacy organizations provide a wealth of information for you to explore on their websites. Many have included a special section devoted to student interests. For example, the ASHP website provides information about career planning and preparation, professional and leadership development, and other education resources for students.

KEY POINT . . .

You can always work with your faculty and administrators to develop your own personal track, arranging a portfolio of practice experiences that will allow you to be competitive when seeking a residency.

. . . SO WHAT?

Do not wait for others to give you what you need to compete for a residency. Take control by making your own arrangements. In fact, a candidate who shows enough drive to build his or her own portfolio of practice experiences may be looked at more favorably than one who simply follows a pathway established by others.

DEVELOPING A CAREER PLAN

No matter what you plan to do after graduation, career planning should consider the acquisition of skills common to hospital and health-system practice, because many of these skills are transferrable to other jobs. Training in health systems provides many chances to develop clinical pharmacy skills—expertise that is transferable to any arena of pharmacy

practice including long-term care, ambulatory pharmacy, and managed care. Training in sterile product preparation and admixtures can be useful in home healthcare and hospice settings. Other skills learned in hospital and health-system settings include the ability to work with teams of professionals, managing technicians, medication distribution systems, and electronic data management.

One way of communicating your commitment to a particular career path is to put it at the beginning of your resume or curriculum vitae in the form of a *career objective*. A few examples of career objectives include (1) to obtain a pharmacy intern position; (2) to obtain a pharmacy practice residency position; (3) to obtain a pharmacist position in a health-system practice setting; and (4) to obtain a clinical pharmacist specialist position. Whether a career objective is necessary on a resume is open to debate; nevertheless, having a career objective gives direction to one's career efforts.

You may want to expand details about your career intentions with a *personal statement*. Personal statements may be asked for when applying for a residency, fellowship, or graduate program. Sometimes a personal statement is explicitly required in the application process. Other times it might be asked in interviews in response to open-ended questions such as, "What led you to choose a career in pharmacy?" or "How will this program help you reach your professional goals?" Your statement should be original and sincere. You can reflect on how your education and practice experiences have contributed to your personal and professional growth. Don't fail to mention specific strengths such as leadership or communication skills and offer a few specific examples or anecdotes that support your points. Finally, avoid repeating information that is readily available in your **resume**, **curriculum vitae (CV)**, or electronic **portfolio**.

GRADUATE EDUCATION

Graduate education is an alternative career option that does not receive as much attention as the residency path. A graduate degree provides unique training and development of skills not typically acquired in residencies. Indeed, some residencies are combined with master's degree programs to

KEY POINT . . .

Many individuals who started in hospitals and other health-system settings now work for pharmacy benefits managers, pharmaceutical companies, state and federal agencies, and more.

. . . SO WHAT?

The skills developed by hospital pharmacists can be transferred to a lot of other settings. New pharmacists who start work in health-system settings have many different alternative career paths open to them as experience is gained.

KEY POINT . . .

Seek the advice of others, but take all career recommendations from others "with a grain of salt." Obtaining advice from experienced individuals can be invaluable, but listen to it with a critical ear because many well-meaning individuals give bad advice. And even when the advice is good, it may not be right for your circumstances.

. . . SO WHAT?

When talking to almost any successful pharmacist about how they chose their career path, the pharmacist will likely describe a conversation or series of conversations with an individual who gave some guidance. The successful pharmacist probably also received a lot of advice that was not heeded. Indeed, sometimes success is determined not only by the advice which is taken but also by the advice which is ignored.

address some of the didactic deficiencies of residencies. **Table 19-4** provides a comparison of the residency with common graduate degree options available to pharmacists.

Many pharmacists pursue graduate degrees on a part-time basis after graduating, often with financial assistance from their employer. Others pursue graduate certificates that provide additional expertise (e.g., board certification in pharmacotherapy, graduate certificate in gerontology).

RESIDENCIES

Completion of a residency is increasingly becoming necessary when pursuing health-system practice positions. Although there are many paths to careers in health-system practice, residency experience is essential for many entry-level positions.

A residency experience provides an accelerated path to skill development and training that would take many more years to achieve without a residency. Upward promotion in some facilities may be hindered without a residency, especially if one is required or preferred for employment.

However, individuals who pursue residency experiences need to make a personal commitment to dedicate themselves to an additional year or two of residency after pharmacy school. Personal factors such as limitations in geographic location, debt burden, weak academic performance, and limited practice experience may serve as deterrents to pursuing residencies. Another consideration is the availability of residencies, the type of hospital and health-system practice setting where you want to work, and other opportunities available to you after graduation.

Postgraduate Year 1 Residency Programs

A residency is designed to build on what pharmacy graduates learned in their doctor of pharmacy degree program. The postgraduate year 1 (PGY1) pharmacy residency program attempts to train pharmacists to be *generalists* who can provide patient medication therapy management in a broad range of therapeutic areas.

Most residencies last for one year, starting on July 1st. Residents complete a variety of structured clinical rotations and other learning activities. Residents learn to work in inter-professional teams to provide direct patient care. Residents have oversight from residency mentors but are given direct responsibility for patient care.

Residents typically work with the program director to create a self-development plan that can tailor the year-long experience to the resident's career goals. This is done through both required and elective rotations. Residents are also required to periodically act as a front-line pharmacist to learn about medication distribution processes that can help in performing clinical duties.

Most residents help precept pharmacy students, and all residents complete a residency project. The project varies depending on the institution's needs, but it is a type of extensive project that is mutually chosen by both the resident and residency mentor. The project is an opportunity for the resident to demonstrate numerous skills like critical thinking, verbal and written communication, data analysis, and time management. Residents present their results at regional residency conferences and often create a manuscript for publication before completing the residency.

Postgraduate Year 2 Residency Programs

The postgraduate year 2 (PGY2) pharmacy residency program builds on the PGY1 experience to focus on a specialized area of practice. Often called a *specialized residency*, it might

TABLE 19-4.

Advanced Training Opportunities for Pharmacists

	Description	Average Time to Complete	Career Opportunities
PharmD	Professional degree that prepares individuals to obtain a pharmacy license to practice pharmacy.	2 to 4 years of pre-pharmacy; 4 years of pharmacy	Staff pharmacist positions in hospital, community, long-term care, mail order, and managed care settings. People with PharmD degrees can gain supervisory and pharmacy management positions with practice experience. This prepares students for 80% of current jobs available in pharmacy. Staff pharmacists may be excluded from many managerial, clinical, and academic opportunities without advanced training.
Residency	Practical training experience that permits residents to attain high levels of professional and clinical expertise.	1 to 2 years beyond PharmD	Residencies prepare pharmacists for advanced practice pharmacist positions in hospital, community, long-term care, mail order, and managed care settings. Often a requirement for managerial and clinical positions in healthcare systems and a prerequisite for most fellowships.
Fellowship	Research training experience that also provides advanced clinical and teaching experience. Typically specializes in a therapeutic area of focus.	2 years beyond residency	Fellowships prepare individuals to work in education (often in a tenure line position), industry (clinical liaison or researcher), or government (Food and Drug Administration [FDA]). In comparison to the PharmD/MS degree program, the fellowship offers greater depth of research and training in a specialty area, but less course work and no graduate degree.
Master of Science (MS)	Graduate degree program that trains students to attain advanced knowledge and research expertise.	2 years beyond PharmD	This degree prepares students to conduct basic research (e.g., clinical trial, practice intervention, database study). The skills learned in attaining this degree prepares individuals for pharmaceutical industry, health system management, governmental positions (e.g., FDA), managed care, and some academic positions.
Master's in Business Administration (MBA)	Professional managerial degree that trains individuals in finance, accounting, marketing, management, and other fields of business.	2 years beyond PharmD	Prepares individuals for managerial positions in any business, including pharmacy and healthcare. Careers include director of pharmacy, health-system management, corporate chain pharmacy management, entrepreneurial business opportunities, pharmaceutical industry management, and governmental positions.

TABLE 19-4. (CONT'D)
Advanced Training Opportunities for Pharmacists

	Description	Average Time to Complete	Career Opportunities
Master's in Public Health (MPH)	Graduate degree that trains individuals to develop, manage, and evaluate health programs for patient populations.	2 years beyond PharmD	The MPH program provides students with the skills for employment in leadership roles in a broad range of local, state, and national public health agencies as well as health systems and managed care.
Doctor of philosophy degree (PhD)	This is a research degree and is the highest educational degree possible. Graduates attain high levels of research and analysis capabilities.	4 years beyond PharmD	This program prepares individuals for any opportunity they wish to pursue. Many of the highest level officials in government, academia, consulting, and industry have PhDs. The degree has significant prestige, and the skills associated with it are highly sought out by employers. Career opportunities are global.
Certificates (e.g., gerontology)	A program of coursework for individuals with a PhD, master's, or bachelor's degree in a defined topic area.	Varies	Provides individuals with additional training and credentials in a specific area of practice.

focus on therapeutic areas such as ambulatory care, critical care, infectious diseases, or oncology. Alternatively, the PGY2 residencies may offer specialized training in managed care pharmacy systems, informatics, and healthcare administration. Some PGY2 residencies are combined with research fellowships and master's degrees.

There are many sources to learn about residency options and ways to pursue them. Extensive discussion is available in the suggested reading section of this chapter.



SUMMARY

The steps you took to become a successful student pharmacist will be similar to those needed to become a successful pharmacist. You should expect that your career goals will change throughout your career. Continue to document your professional activities and achievements by routinely updating your resume, CV, or electronic portfolio. Continue to reassess your career goals and determine if your current career path is allowing you to achieve what you want. Make a commitment to lifelong learning and seek to enhance your knowledge and skills as you progress throughout your career.

SUGGESTED READING

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CHAPTER REVIEW QUESTIONS

1. **A pharmacy graduate needs a residency to become a health-system pharmacist.**
 - a. True
 - b. False

Answer: b. False. A residency is not an absolute requirement to become a health-system pharmacist, but it is becoming increasingly important. All things equal, the candidate with a residency will be preferred over a candidate without residency experience. And the candidate with a residency may have a better choice of positions. Nevertheless, many new graduates get jobs in health systems without residency training. Many factors go into the hiring of pharmacists, and residency training is just one.

2. **I am about to graduate from a Doctor of Pharmacy program. I really want to work as a hospital pharmacist, but I was thinking of working for a community pharmacy chain first until I pay off my student loans. Then I would look for a hospital job. Is this a good idea?**
 - a. Yes
 - b. No
 - c. Maybe
 - d. Probably not

Answer: d. Probably not, for at least two good reasons. One is that postponing what you really want to do, for whatever reason, might lead you to put off your plans forever. If you want to be a hospital pharmacist, be a hospital pharmacist. Another reason to start your career as a hospital pharmacist is that the skills and training that prepare a person to succeed in chain pharmacy practice are different from the skills and training needed for hospital pharmacy. Therefore, it might be harder to switch to hospital pharmacy than you might think.

3. I do not know what I want to do with my life. Should I get an MBA?

- a. Yes
- b. No
- c. Maybe
- d. Probably not

Answer: c. Maybe. If you do not know what to do with your life, experimenting with different career options is a good idea. Formal management training is one option. However, MBA training may be more beneficial if one has an idea about how it might be used. Rather than spend money on further education, another option might be to learn as much as possible in entry-level training by volunteering for additional experiences and on-the-job education.

4. Which is the better graduate degree?

- a. MBA
- b. MPH
- c. MS

Answers: a, b, or c. depending on what you want to do with that degree. An MBA is a general business degree that educates people to be a manager in a business. MBAs do not typically focus on healthcare problems or issues of healthcare. That can be advantageous if it helps health professionals to think outside the box and examine problems in new ways (e.g., using hotel management techniques to solve hospital service issues). But it can be a disadvantage by teaching topics that may not be particularly relevant to hospital and health-system practice and not educating about critical healthcare issues (e.g., formulary systems, pharmacoeconomics). A MPH is a good alternative to a MBA because it trains pharmacists in epidemiology and public health. MS degrees in pharmacy administration or pharmacotherapy are other good options because they can usually be tailored to the career interests of students. Discussion of MS, MBA, and MPH degree programs are beyond the scope of this chapter. Interested individuals can find information about different programs on the Internet or by talking with faculty members at your school.

5. Which is the better choice regarding when to enter into a graduate program?

- a. Go straight into a graduate program after pharmacy school.
- b. Work for a while before applying to graduate school.

Answers: a or b. Once again, the answer depends on your situation. Many individuals, who wait to go back to graduate school, never do. Life's needs and desires or complacency may get in the way. Then again, working for a while after graduation can help pharmacists identify career opportunities and develop work experience that can be applied to what is learned in graduate school.

6. Compensation packages in health-system practice are much less than community pharmacy.

- a. True
- b. False

Answers: a or b. The answer to this depends on the geographic location and local job market. Some people automatically assume that chain pharmacies offer better compensation packages, a potentially false assumption. The only way to be sure is to compare them. And if the difference is large, it would be reasonable to ask why it takes so much more money to attract professionals to chain practice. It should be noted that compensation packages (i.e., salary, benefits) are just one consideration when choosing a pharmacy

employer. Other important considerations are the potential for professional development and quality of work life.

7. My parents want me to start working after graduation at a well-known community pharmacy chain, but I am thinking about doing a residency. What should I do?

- a. Listen to your parents—they know what is best for you.
- b. Listen to your parents, but make your own decision.
- c. Don't listen to your parents about issues related to your career path.

Answer: b. Listen to your parents, but make your own decision. Your parents may love you and want the very best for you, but you need to make your own decisions. You are the best person to understand what you want and need in a career.

8. What is the best way to get into hospital and health-system pharmacy practice?

- a. Complete a residency.
- b. Gain hospital and health-system pharmacy internship experience.
- c. Get a MBA.
- d. Network with hospital and health-system pharmacists.
- e. None of the above

Answer: e. None of the above. There is no “best” way. The paths to hospital and health-system practice are varied.

9. I didn't like my initial health-system professional practice experience. Is this what health-system practice is like?

- a. Yes
- b. No
- c. Maybe
- d. Probably not

Answer: d. Probably not. Each health-system setting is different, so a bad experience at one setting may not be representative of all practice settings. Do not let a bad experience color your whole opinion of this kind of practice.

10. Which degree is the highest educational degree possible?

- a. MPH
- b. MS
- c. MBA
- d. PhD

Answer: d. The PhD is a research degree that prepares graduates with the ability to conduct complex research and analysis.

CHAPTER DISCUSSION QUESTIONS

1. Is clinical pharmacy the only career path with any future in health-system pharmacy practice?
2. What are the positives and minuses of specializing (e.g., oncology) versus choosing a less specialized area of practice (e.g., ambulatory care)?
3. Will all pharmacists need a residency in the future? Why or why not?
4. What advantages do advanced degrees like the MPH, MS, MBA, and PhD have for one's career?
5. Which is easier—going from community practice to hospital pharmacy or vice versa?

Career Options for Technicians in Hospitals and Health Systems

Jennifer Phillips and Carrie A. Sincak

LEARNING OBJECTIVES

After completing this chapter, readers should be able to:

1. Explain how the role of a pharmacy technician has evolved over time.
2. Identify the training and certification required for pharmacy technicians.
3. Explain how pharmacy technicians may be involved in the ASHP Practice Advancement Initiative (PAI).
4. Discuss the various career options for pharmacy technicians in hospitals and health systems.

KEY TERMS AND DEFINITIONS

- **Accreditation:** An organization's recognition and approval verifying a program has maintained and complied with expected standards. Accreditation is the approving organization's process for certifying competency and quality.
- **Certification:** Recognition granted to an individual (e.g., pharmacy technician) or organization (e.g., technician training program) that has demonstrated competency for a certain level of knowledge and skill in an area of pharmacy practice or training. An organization, such as the Pharmacy Technician Certification Board, grants this recognition after an exam or assessment of training processes.
- **Credentialing:** A credential is a document (e.g., license, certification) that provides evidence of an individual's qualifications. *Credentialing* is a formal review of qualifications of a technician or other healthcare professional who wants to be given specific responsibilities in a health system.
- **Medication reconciliation:** Process of obtaining current medications the patient is taking and comparing to the patient's medication list to create the most accurate list possible.
- **Pharmacy Advancement Initiative (PAI):** Name changed from Pharmacy Practice Model Initiative (PPMI) to PAI to make the initiative more comprehensive to include all practice settings and make involvement of pharmacy personnel, not just management, all inclusive.
- **Pharmacy Practice Model Initiative (PPMI):** An ASHP-created movement that encourages the pharmacy team to focus on patient-centered care to improve patient outcomes in hospitals and health-system settings.
- **Pharmacy technician:** A healthcare professional who assists in the practice of pharmacy under the supervision of a licensed pharmacist.
- **Pharmacy Technician Certification Board (PTCB):** Board that nationally certifies pharmacy technicians through a certification exam to advance patient safety. It is governed by the American Pharmacists Association, ASHP, Illinois Council of Health-System Pharmacists, Michigan Pharmacists Association, and National Association of Boards of Pharmacy.
- **Practice at the top of one's license:** This refers to licensed healthcare providers such as pharmacists who practice to the full extent of their education and training instead of doing things that can be successfully completed by others with less training.



INTRODUCTION

The goal of this chapter is to provide an overview of the range of roles for **pharmacy technicians** in the health-system and ambulatory care environments. Having an understanding of the training requirements and abilities of pharmacy technicians may aid students (as future pharmacists) in gaining a deeper understanding of how they can work with technicians more effectively in the workplace now and in the future.

Based on census data from the National Associations of Boards of Pharmacy and the Bureau of Labor and Statistics, there are over 400,000 pharmacy technicians in the United States with a prediction of a 9% increase in projected employment from 2014–2024.¹ The need for pharmacy technicians will continue to rise with the ever-growing geriatric population and the increase in the number of prescription medication use.²

Historically, the role of the pharmacy technician was to assist in the dispensing of medications. A pharmacy technician was defined as “an individual working in a pharmacy [setting] who, under the supervision of a licensed pharmacist, assists in pharmacy activities that do not require the professional judgment of a pharmacist.”³ **Figure 20-1** depicts the history of the pharmacy technician profession and how it has evolved. Over time, duties increased to involve prescription order entry, managing third-party payers, and overseeing inventory control. Health-system pharmacy technicians may have additional responsibilities such as preparing intravenous admixtures and handling investigational drugs.⁴ As the scope of practice expanded and the national shortage of pharmacists increased, the profession had to turn to pharmacy technicians to help fill the void needed to fulfill the distributive function.

As the profession of pharmacy continues to evolve and pharmacists’ services continue to expand, the role of pharmacy technicians will also evolve and continue to be an integral piece to advancing the pharmacy practice model. For pharmacists to provide exceptional patient care, pharmacy technicians are key in the pharmacy’s distributive and operational functions. Pharmacy technicians work closely with pharmacists to prepare and distribute prescription medications to patients in a variety of settings, including health-system and community pharmacies.

KEY POINT . . .

The role of the pharmacy technician continues to evolve to ensure pharmacists are able to focus less on distributive functions and more on advancing clinical services for patients in the healthcare system.

. . . SO WHAT?

Opportunities for pharmacy technicians continue to grow as they accept greater responsibility for nonclinical roles in healthcare. Individuals who are willing to move beyond their traditional roles can thrive in the pharmacy profession.

OVERVIEW OF ACCREDITATION/TRAINING/CREDENTIALING/LEGAL REQUIREMENTS

Laws surrounding the training, licensing, and **certification** of pharmacy technicians differ considerably by state. Eighteen states do not require licensing or certification of pharmacy technicians but require registration.⁵ Delaware, Ohio, and Wisconsin do not license, register, or certify pharmacy technicians.⁵ Other items such as the ratio of technician-to-pharmacist in an ambulatory care or institutional setting, and duties that technicians are allowed to perform also vary greatly by state. In addition, 14 states and Guam do not have

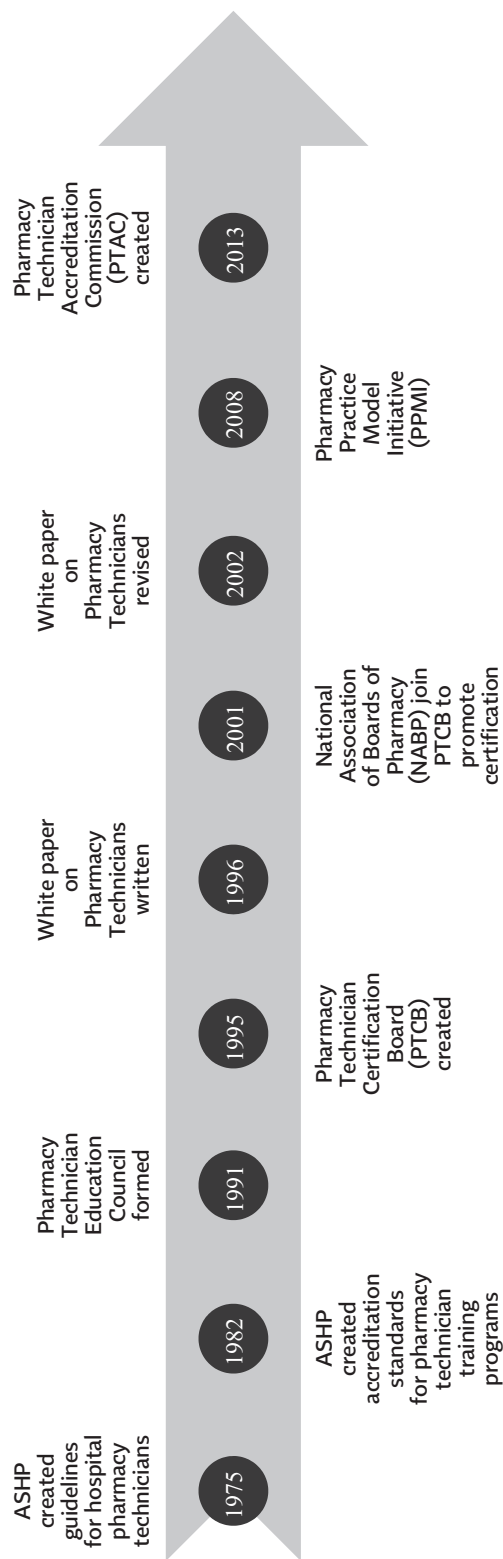


FIGURE 20-1. Historical Timeline of Pharmacy Technicians

any technician training requirements.⁵ Pharmacy technicians who do not have formal pharmacy technician education typically learn their skills on the job.

For those states requiring some sort of pharmacy technician education or training, the programs vary. These programs are usually affiliated with a community college, university, or healthcare organization. Most of them have a didactic component followed by experiential training.⁶ Standards for these programs may also be different based on **accreditation**. Accreditation standards are used to establish minimum criteria necessary to deliver a quality educational program. Similar to colleges of pharmacy, pharmacy technician programs may also be accredited. The Pharmacy Technician Accreditation Commission (PTAC), a collaboration between the American Society of Health-System Pharmacists (ASHP) and the Accreditation Council for Pharmacy Education, serves as the accrediting review committee for pharmacy technician education programs. PTAC is also responsible for the review, update, and revision of the pharmacy technician accreditation standards.^{6,7}

The **Pharmacy Technician Certification Board (PTCB)** and the National Healthcareer Association (NHA) both offer national certification exams for pharmacy technicians and are accredited by the National Commission for Certifying Agencies (NCCA). The PTCB exam is the PTCE (Pharmacy Technician Certification Exam), and the NHA exam is the ExCPT (Exam for the Certification of Pharmacy Technicians). The PTCE is more widely recognized by states across the country and has been around longer; therefore, it is more established. Many more technicians are PTCE-certified than ExCPT-certified. Certification allows technicians to prove that they have mastered a certain skill or core of knowledge that may result in a broader scope of technician responsibilities.

TRADITIONAL TECHNICIAN ROLES

Pharmacy technicians are support professionals who assist pharmacists by completing tasks that are important and necessary in the drug use and distribution process but do not require the professional judgment of a pharmacist. A pharmacist, who is accountable and legally responsible for the technician-performed tasks and activities, reviews those tasks for accuracy.⁸ By assisting with these types of tasks, pharmacy technicians can free up time for the pharmacist to concentrate on other tasks that require more clinical judgment. The roles and responsibilities of a pharmacy technician may vary based on the job location (i.e., ambulatory versus hospital), institution-specific policies and guidelines, as well as legal requirements, which often differ by state. In addition to legal and institutional policy, it is important to consider the individual technician's experience and/or training when deciding what types of responsibilities can be appropriately delegated, since the amount of training and experience may vary from person to person.

Table 20-1 lists typical tasks that pharmacy technicians perform in institutional, community, and ambulatory care settings. In recent years, cost-containment pressures have resulted in increased utilization of outpatient treatment facilities for minor surgical procedures or invasive tests. Whereas in the past, patients would have been admitted to the hospital for a procedure, this is being done more frequently as an outpatient. Consequently, pharmacists working in outpatient surgery centers or outpatient clinics may utilize pharmacy technicians to assist with a variety of tasks (see Table 20-1).

CHANGING LANDSCAPE—PPMI/PAI

The **Pharmacy Practice Model Initiative (PPMI)** was launched in 2008 with the primary goal of encouraging pharmacy leaders to re-examine resource allocation, specifically as it pertains to pharmacist time, technician time, and technology, to ensure that the most urgent needs of the patients and the institutions were met.¹¹ Participants of the PPMI

TABLE 20-1.

Tasks Performed by Pharmacy Technicians by Setting

Setting	Typical Tasks
Hospital Setting	<ul style="list-style-type: none">■ Preparing sterile dosage products (e.g., IV, TPN)■ Loading medications into an automated dispensing cabinet (e.g., Pyxis, Omnicell)■ Delivering medications to a patient care unit■ Maintaining inventory and dispensing records for controlled substances■ Compounding medications■ Packaging drugs■ Record keeping■ Managing inventory■ Packaging or re-packaging medications■ Entering physician orders into a pharmacy computer system■ Sanitizing, calibrating, or otherwise maintaining equipment■ Assisting with drug recalls■ Answering/triaging phone calls
Community	<ul style="list-style-type: none">■ Answering/triaging phone calls from patients or providers■ Accepting prescriptions from customers and screening for inclusion of all necessary information■ Accurately typing labels for prescription bottles■ Entering patient information into the computer system (e.g., prescription information, allergies, address, health history, and previous medications)■ Affixing appropriate auxiliary labels to final packaging■ Managing inventory■ Managing a cash register
Ambulatory Care	<ul style="list-style-type: none">■ Answering/triaging phone calls from patients or providers■ Maintaining inventory of samples and medical equipment■ Managing recalls for samples and medical devices or supplies■ Communicating with providers and patients■ Assisting pharmacists in monitoring patient outcomes■ Managing billing and insurance issues

IV: intravenous; TPN: total parenteral nutrition
See references 4, 9, and 10 for more information.

Summit noted that pharmacy technicians, with the appropriate education and training, could be utilized much more extensively to help pharmacists spend less time doing distributive functions. Therefore, participants at the summit recommended that all tasks not requiring the clinical judgment of a pharmacist be assigned to pharmacy technicians.¹² In 2015, the PPMI was re-branded as the **Pharmacy Advancement Initiative (PAI)** to reflect a more broad range of pharmacist services, including those provided in the ambulatory care setting.¹³ Similar to the PPMI Summit, the Recommendations of the ASHP Ambulatory Care

Summit also recommend optimizing the role of pharmacy technicians in the ambulatory care environment.¹⁴

EVOLVING ROLES FOR PHARMACY TECHNICIANS

In addition to the more traditional responsibilities outlined above, there are a number of unique roles for pharmacy technicians that have evolved. The following is a summary of some of these novel job responsibilities:

- **Tech-check-tech** — Many states now allow a trained pharmacy technician to verify the accuracy of unit dose medications filled by another technician in an institutional setting with the use of approved protocols. This process, known as tech-check-tech (TCT), frees up time for the pharmacists to concentrate on more clinical tasks. Studies have shown that the accuracy rate of pharmacy technicians is comparable to or better than that of a pharmacist in this capacity.¹⁵⁻²²
- **Medication reconciliation** — Another emerging role for pharmacy technicians is in the area of medication reconciliation. Many studies have highlighted the positive impact of utilizing pharmacy technicians in the medication reconciliation process to take patient histories or assist with admission, transfer, or discharge reconciliation.²³⁻²⁷ The value of a pharmacy technician's medication reconciliation has also been demonstrated in the outpatient setting, with studies showing a benefit in the preoperative setting and emergency department areas.²⁸⁻³⁰
- **Teaching** — Pharmacy technicians may also play a role in training/educating other pharmacy technicians, other healthcare professionals, and even pharmacy students. A recently published study indicated that pharmacy students are generally receptive to learning certain distributive tasks of the medication-use process from pharmacy technicians and that pharmacy technicians feel comfortable in this role.³¹
- **Advanced ambulatory roles** — Pharmacy technicians, for example, have helped to improve osteoporosis management. One study found that pharmacy technicians saved pharmacists' time when developing osteoporosis care plans by assisting with retrieval and classification of clinical information from patient records.³²

KEY POINT . . .

The Pharmacy Advancement Initiative supports more extensive roles for pharmacy technicians who have appropriate education, training, and credentials; this will allow pharmacists to focus on clinical services rather than drug distribution activities.

. . . SO WHAT?

The pharmacy profession is fully behind expanding opportunities for pharmacy technicians. Pharmacists want technicians to be active members of the healthcare team.

KEY POINT . . .

Pharmacy technicians are essential to the pharmacy operation. Their roles have evolved greatly over time; and with the pharmacy profession's continuing advancement, the need for expanding roles of pharmacy technicians will also increase.

. . . SO WHAT?

Pharmacy technicians will need to continually update their skill as their responsibilities increase. On-the-job training and formal education will be required to keep pace with developments in pharmacy practice and healthcare.

- **Medication safety** — Pharmacy technicians have been utilized to assist with medication safety initiatives including reporting, investigating, and communicating information about adverse drug reactions and/or medication errors; assisting with data collection; and running or analyzing reports.³³
- **Leadership** — Pharmacy technicians can serve in many formal and informal leadership roles within the health-system and ambulatory care settings. As an informal leader, technicians can assume the role of a *pharmacist extender* by working as part of an interdisciplinary team.³⁴ Some of these responsibilities may include triaging phone calls, organizing/overseeing workflow, scheduling, entering in patient demographic information, and assisting with discharge medication delivery. Some technicians also adopt formal leadership roles such as technician supervisor, inventory manager, or information technology lead.
- **Other roles** — As technology evolves, technicians are increasingly utilized to assist with inventory management, quality improvement initiatives, billing, automation maintenance, and data management. Technicians are also assisting pharmacists who conduct research.³⁵

Overview of Salary

In 2014, the average hourly rate for a pharmacy technician was \$14.33/hour (\$29,810 annually).³⁶ In comparison, the average hourly rate for a pharmacist in 2014 was four times that of technicians—\$58.15/hour (\$120,950 annually).³⁷ When pharmacists participate in roles that technicians can effectively accomplish, opportunities to enhance clinical care and reduce costs are missed.

Some pharmacists are hesitant about delegating more responsibility to a pharmacy technician out of fear of being replaced by a much less expensive resource. These pharmacists, in fact, may be replaced if they are unwilling to take on greater clinical responsibilities. Most pharmacists see the expanded training and utilization of pharmacy technicians as opportunities to **practice at the top of their license**, and most pharmacists believe pharmacy technicians have a positive impact on the advancement of the profession. There are many responsibilities allocated to pharmacists that do not require clinical judgment. Other healthcare professions, such as physicians and dentists, have done a good job of delegating clerical or nonclinical tasks to assistants or care extenders (e.g., dental hygienists, nurses, care managers, billing personnel), which helps free up their time for more complex patients or issues. Similarly, pharmacy technicians can help pharmacists become more involved members of the healthcare team.



SUMMARY

The role of the pharmacy technician is instrumental to advancing the profession of pharmacy. As their roles continue to evolve over time, technicians should be considered valuable supportive members of the healthcare team. With appropriate guidance, training, and education, these individuals can help to improve the quality of the medication-use process and advance the role of pharmacists as pivotal members of the healthcare team.

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CHAPTER REVIEW QUESTIONS

1. **Requirements for licensure and registration of pharmacy technicians are standard across all states.**

- a. True
- b. False

Answer: b. False. Current rules and regulations concerning licensure and registration vary from state to state. There is no universal standard regarding licensure or registration for pharmacy technicians within pharmacy law.

2. **The Pharmacy Technician Certification Board (PTCB) will require candidates to do the following:**

- a. Be involved in counseling by 2020.
- b. Complete any training program by 2020.
- c. Be involved in point-of-care testing by 2020.
- d. Complete an ASHP-accredited training program by 2020.

Answer: d. PTCB will require technicians to complete an ASHP-accredited training or education program beginning in 2020. This will allow a movement toward standardized training, similar to standards required to become a licensed pharmacist.

3. **The process by which one pharmacy technician verifies the accuracy of unit dose medications filled by another pharmacy technician is known as:**

- a. Medication reconciliation
- b. Order verification
- c. Inventory management
- d. Tech-check-tech

Answer: d. Tech-check-tech allows a pharmacy technician to verify another pharmacy technician's unit dose filling. This increased job responsibility allows pharmacists to focus on more clinical services.

4. **The Pharmacy Practice Model Initiative (PPMI) and Pharmacy Advancement Initiative (PAI) recommend using pharmacy technicians more extensively to improve efficiency of the medication-use process.**

- a. True
- b. False

Answer: a. True. This model or initiative will allow efficiency in the medication-use process that will result in quality improvement to enhance patient outcomes.

5. **Studies highlighting the value of using pharmacy technicians to assist with medication reconciliation have been conducted in which of the following areas?**

- a. Inpatient
- b. Ambulatory Care
- c. Emergency Room
- d. Pre-operative setting
- e. All of the above

Answer: e. All of the above. Studies involving pharmacy technicians in medication reconciliation have shown value in all of the above areas.

6. What is the main reason to expand the scope of practice for pharmacy technicians?

- a. Meet the rise of the growing pediatric population.
- b. Meet the expanding scope of practice for pharmacists.
- c. Perform clinical duties of a pharmacist when there is a shortage.
- d. All of the above

Answer: b. Meet the expanding scope of practice for pharmacists. Pharmacy technicians will help fill the void needed to perform the medication distributive functions as the scope of pharmacists expand.

7. In what types of practice settings will you find pharmacy technicians?

- a. Community
- b. Hospital
- c. Ambulatory Care
- d. Quality and Safety
- e. All of the above

Answer: e. All of the above. Pharmacy technicians typically perform in community and institutional settings, but their scope has expanded to different areas.

8. What certification exam may a pharmacy technician take to demonstrate advanced skill?

- a. Pharmacy Advancement Exam
- b. Pharmacy Practice Model Exam
- c. Pharmacy Technician Certification Exam
- d. Pharmacy Credentialing Exam

Answer: c. Pharmacy Technician Certification Exam. This is a national exam that certifies pharmacy technicians to advance patient safety.

9. A pharmacy technician must be a certified pharmacy technician (CPhT) in order to perform medication reconciliation.

- a. True
- b. False

Answer: b. False. Pharmacy technicians do not have to be certified to perform medication reconciliation. However, certification of these technicians proves they have mastered a certain skill or core of knowledge to effectively perform such a responsibility.

10. Which of the following factors explains why the role of technicians has expanded over time?

- a. The scope of pharmacists' duties expanded.
- b. There was a national shortage of pharmacists.
- c. Studies demonstrated that technicians could perform some tasks as well as pharmacists.
- d. All of the above.

Answer: d. All of the above. The scope of pharmacists' responsibilities increased dramatically over the last 20 years. This, combined with a shortage of pharmacists in the 1990s and early 2000s as well as the increase in our aging population, led to a demand to fulfill distributive functions. In addition, quality assurance studies demonstrated that technicians could perform certain distributive tasks as well as practicing pharmacists.

CHAPTER DISCUSSION QUESTIONS

1. What type(s) of pharmacy-related responsibilities do you think can be safely delegated to a pharmacy technician?
2. What type(s) of responsibilities do you think should be performed only by a pharmacist?
3. How do you think the role of pharmacy technicians will evolve over the next 15–20 years?
4. Should there be mandatory education requirements for pharmacy technicians?
5. What type of leadership roles can pharmacy technicians serve within the pharmacy profession?

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